No. 15-1195
Vide 15-1039

Title:	Amgen Inc., et al., Petitioners v. Sandoz Inc.
Docketed:	March 23, 2016
Lower Ct:	United States Court of Appeals for the Federal Circuit
Case Nos.:	(2015-1499)
Decision Date:	July 21, 2015
Rehearing Denied:	October 16, 2015

Questions Presented

~~Date~~~	~~~~~~~Proceedings and Orders~~~~~~~~~~~~~~~~~~~~
Mar 21 2016	Petition for a writ of certiorari filed. (Response due April 22, 2016)
Apr 18 2016	Order extending time to file response to petition to and including May 17, 2016.
May 17 2016	Brief of respondent Sandoz Inc. in opposition filed.
May 27 2016	Reply of petitioners Amgen Inc., et al. filed.
May 31 2016	DISTRIBUTED for Conference of June 16, 2016.
Jun 20 2016	The Solicitor General is invited to file a brief in this case expressing the views of the United States.
Dec 7 2016	Brief amicus curiae of United States filed. VIDED.
Dec 20 2016	Supplemental brief of petitioners Amgen Inc., et al. filed. VIDED.
Dec 21 2016	DISTRIBUTED for Conference of January 6, 2017.
Jan 9 2017	DISTRIBUTED for Conference of January 13, 2017.
Jan 13 2017	Petition GRANTED. The petition for a writ of certiorari in No. 15-1039 is granted. The cases are consolidated and a total of one hour is allotted for oral argument.
Jan 25 2017	The following briefing schedule is adopted: Petitioner in No. 15-1039 will file an opening brief limited to the question presented in its petition, not to exceed 15,000 words, on or before Friday, February 10, 2017. Petitioners in No. 15-1195 will file a consolidated opening brief on the question presented in their petition and response brief, not to exceed 19,000 words, on or before Friday, March 10, 2017. Petitioner in No. 15-1039 will file a consolidated response brief and reply brief, not to exceed 10,000 words, on or before Friday, March 31, 2017. Petitioners in No. 15-1195 will file a reply brief, not to exceed 6,000 words, on or before Friday, April 14, 2017. Any brief of an amicus curiae in support of petitioner in No. 15-1039 or in support of neither party is to be filed on or before Friday, February 17, 2017, and the brief should bear a light green cover. Any brief of an amicus curiae in support of petitioners in No. 15-1195 is to be filed on or before Friday, March 17, 2017, and the brief should bear a dark green cover. An amicus curiae may file only a single brief in these cases. VIDED.
Jan 30 2017	Joint motion of the parties to dispense with printing the joint appendix filed. VIDED.
Feb 17 2017	SET FOR ARGUMENT ON Wednesday, April 26, 2017. VIDED.
Feb 17 2017	Brief amici curiae of Apotex Inc. and Apotex Corp. filed. VIDED.
Feb 17 2017	Brief amicus curiae of Coherus Biosciences, Inc. filed. VIDED.
Feb 17 2017	Brief amicus curiae of America's Insurance Health Plans filed. VIDED.
Feb 17 2017	Brief amicus curiae of United States filed. VIDED.

Feb 17 2017	Brief amicus curiae of Biosimilars Council filed. VIDED.
Feb 17 2017	Brief amicus curiae of Mylan Inc. filed. VIDED.
Feb 21 2017	Motion to dispense with printing the joint appendix filed by petitioners GRANTED. VIDED.
Feb 24 2017	Record requested from the U.S.C.A. for the Federal Circuit. VIDED.
Mar 10 2017	Opening and Response Brief for Amgen Inc., et al. filed. VIDED.
Mar 17 2017	Brief amicus curiae of AbbVie Inc. filed. VIDED.
Mar 17 2017	Motion of the Acting Solicitor General for leave to participate in oral argument as amicus curiae and for divided argument filed. VIDED.
Mar 17 2017	Brief amici curiae of Eleven Professors filed.
Mar 17 2017	Brief amicus curiae of Janssen Biotech, Inc. filed. VIDED.
Mar 17 2017	Brief amicus curiae of Biotechnology Innovation Organization. filed. VIDED.
Mar 17 2017	Brief amicus curiae of Genentech, Inc. filed. VIDED.
Mar 22 2017	CIRCULATED.
Mar 27 2017	Record received from the U.S.C.A. for the Federal Circuit. The record is available on PACER, except for confidential materials transmitted separately. VIDED.
Mar 31 2017	Consolidated Response and Reply Brief of Sandoz Inc. filed. VIDED. (Distributed)
Apr 13 2017	Motion of the Acting Solicitor General for leave to participate in oral argument as amici curiae and for divided argument GRANTED. VIDED. Justice Gorsuch too no part in the consideration or decision of this motion.
Apr 13 2017	Reply of petitioners Amgen Inc., et al. filed. (Distributed)
Apr 26 2017	Argued. For petitioner in No. 15-1039: Deanne E. Maynard, Washington, D. C.; and Anthony A. Yang, Assistant to the Solicitor General, Department of Justice, Washington, D. C. (for United States, as amicus curiae.) For petitioners in 15-1195: Seth P. Waxman, Washington, D. C. VIDED.
Jun 12 2017	Adjudged to be VACATED IN PART, REVERSED IN PART, and case REMANDED. Thomas, J., delivered the opinion for a unanimous Court. Breyer, J., filed a concurring opinion. VIDED.
Jul 14 2017	JUDGMENT ISSUED.

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15-1195

Supreme Court, U.S.
FILED
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OFFICE OF THE CLERK

IN THE

Supreme Court of the United States

AMGEN INC. AND AMGEN MANUFACTURING LIMITED,

Cross-Petitioners,

v.

SANDOZ INC.,

Cross-Respondent.

ON CROSS-PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

CONDITIONAL CROSS-PETITION FOR A WRIT OF CERTIORARI

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QUESTION PRESENTED

The Biologics Price Competition and Innovation Act of 2009 (the "BPCIA"), *see* Pub. L. No. 111-148, §§ 7001-7003, 124 Stat. 119, 804-21, created a new regulatory pathway, 42 U.S.C. § 262(k), by which the FDA could approve a biologic product as "biosimilar to" a "reference product" that was itself approved under the full, traditional pathway of 42 U.S.C. § 262(a). "[B]alancing innovation and consumer interests," Pub. L. No. 111-148 § 7001(b), Congress established procedures to control and streamline patent litigation between the biosimilar applicant (the "Applicant") and the reference product sponsor (the "Sponsor" or "RPS"), *see* 42 U.S.C. § 262(*l*), triggered by the filing of an application under the new abbreviated pathway, *see id.* § 262(*l*)(1)(B)(i).

Amgen Inc. and Amgen Manufacturing Limited (together, "Amgen") respectfully file this Conditional Cross-Petition for a writ of certiorari to review the judgment of the United States Court of Appeals for the Federal Circuit regarding its interpretation of one part of the integrated patent-litigation procedures in subsection 262(*l*). Specifically, subparagraph 262(*l*)(2)(A) requires that, within 20 days of the FDA accepting its biologics license application for review under the new, abbreviated regulatory pathway, the Applicant "shall provide" the Sponsor with a copy of that biologics license application and related information about the manufacture of its proposed biosimilar product. Despite the statute's use of the mandatory verb "shall" and the centrality of the biologics

QUESTION PRESENTED (CONTINUED)

license application and manufacturing information to many of the steps of the patent-dispute-resolution procedures, the Federal Circuit held that an Applicant is not required to provide that information to the Sponsor and that a court cannot compel an Applicant to provide that information.

The question presented by this Conditional Cross-Petition is:

> Is an Applicant required by 42 U.S.C. § 262(*l*)(2)(A) to provide the Sponsor with a copy of its biologics license application and related manufacturing information, which the statute says the Applicant "shall provide," and, where an Applicant fails to provide that required information, is the Sponsor's sole recourse to commence a declaratory-judgment action under 42 U.S.C. § 262(*l*)(9)(C) and/or a patent-infringement action under 35 U.S.C. § 271(e)(2)(C)(ii)?

Cross-Respondent Sandoz Inc. ("Sandoz") has already filed a petition ("Sandoz's Petition"), which has been docketed as No. 15-1039, asking for this Court to review the Federal Circuit's interpretation of another component of the patent-dispute-resolution procedures of subsection 262(*l*), the notice of commercial marketing required by subparagraph 262(*l*)(8)(A). There, consistent with this Court's statutory-interpretation precedent, the Federal Circuit held that the verb "shall" is mandatory. Notably, Sandoz argues in its petition

QUESTION PRESENTED (CONTINUED)

that subparagraph 262(*l*)(8)(A) is directly connected with the other patent-dispute-resolution procedures of subsection 262(*l*), and ascribes error to the Federal Circuit for "erroneously divorc[ing] the notice of commercial marketing provision from the patent resolution scheme." (Pet. at 31.) For the reasons set forth in Amgen's brief in opposition, the Court should deny Sandoz's Petition. If the Court does so, it should deny this Conditional Cross-Petition too. If, however, the Court grants Sandoz's Petition, it should consider both questions regarding the patent-resolution scheme of the BPCIA by granting this Conditional Cross-Petition as well.

PARTIES TO THE PROCEEDINGS

The caption identifies all parties. Cross-Petitioners are Amgen Inc. and Amgen Manufacturing Limited. Cross-Respondent is Sandoz Inc.

CORPORATE DISCLOSURE STATEMENT

Pursuant to Rule 29.6 of the Rules of this Court, Cross-Petitioners Amgen Inc. and Amgen Manufacturing Limited state the following:

Amgen Inc. is a publicly held corporation. Amgen Inc. has no parent corporation and no publicly held corporation owns 10% or more of its stock.

Amgen Manufacturing Limited is a wholly owned subsidiary of Amgen Inc. Apart from Amgen Inc., there is no publicly held corporation with a 10% or greater ownership in Amgen Manufacturing Limited.

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OPINIONS BELOW

The opinion of the Federal Circuit is reported at 794 F.3d 1347 and is reproduced at pages 1a-55a of the Appendix to Sandoz's Petition in 15-1039 ("Pet. App."). The opinion of the district court is unreported but is available at 2015 WL 1264756 and reproduced at Pet. App. 56a-84a. Pursuant to Supreme Court Rule 12, Amgen has not reproduced the materials included in the Appendix to Sandoz's Petition.

JURISDICTION

The Federal Circuit entered judgment on July 1, 2015. Amgen and Sandoz each petitioned for rehearing en banc, and those petitions were denied on October 16, 2015. (Pet. App. at 85a-86a.) On December 29, 2015, the Chief Justice extended the time for Sandoz to petition for a writ of certiorari to and including February 16, 2016. Sandoz filed its petition for a writ of certiorari, No. 15-1039, on that day, and it was docketed on February 18, 2016. This Conditional Cross-Petition is timely pursuant to this Court's Rule 12.5. This Court has jurisdiction under 28 U.S.C. § 1254(1).

STATUTORY PROVISIONS INVOLVED

The BPCIA, Pub. L. No. 111-148, §§ 7001-7003, 124 Stat. 119, 804-21 (2010), and the relevant provisions of Titles 28, 35, and 42 of the United States Code amended by the BPCIA are reprinted at Pet. App. 87a-163a. Paragraph 262(*l*)(2) of Title 42 provides:

STATUTORY PROVISIONS INVOLVED (CONTINUED)

(2) Subsection (k) application information. Not later than 20 days after the Secretary notifies the subsection (k) applicant that the application has been accepted for review, the subsection (k) applicant—

(A) shall provide to the reference product sponsor a copy of the application submitted to the Secretary under subsection (k), and such other information that describes the process or processes used to manufacture the biological product that is the subject of such application; and

(B) may provide to the reference product sponsor additional information requested by or on behalf of the reference product sponsor.

INTRODUCTION

The Federal Circuit's decision in this case was its first significant analysis of the "patent-dispute-resolution regime" of the BPCIA. (Pet. App. at 6a (citing 42 U.S.C. § 262(*l*).). Subsection 262(*l*) creates "a unique and elaborate process for information exchange between the biosimilar applicant and the RPS to resolve patent disputes." (*Id.*)

The Federal Circuit panel considered two components of that elaborate process, construing one of them as Sandoz had proposed and one of them as Amgen had proposed. These are those components:

Provision of the aBLA Under § 262(*l*)(2)(A): The patent procedures of subsection 262(*l*) commence as soon as the Applicant chooses to file an abbreviated biologics license application ("aBLA" or "subsection (k) application") under the subsection (k) pathway, rather than a full application under the traditional subsection (a) pathway. *See* 42 U.S.C. § 262(*l*)(1)(B)(i). An Applicant that chooses to avail itself of the benefits of the subsection (k) pathway—including referencing the Sponsor's license and clinical trial data—must provide to the Sponsor the information that is the foundation of the exchange procedures:

> When a subsection (k) applicant submits an application under subsection (k), such applicant shall provide to the [Sponsor], subject to the terms of this paragraph, confidential access to the information required to be produced pursuant to

> paragraph (2) and any other information that the subsection (k) applicant determines, in its sole discretion, to be appropriate (referred to in this subsection as the "confidential information").

42 U.S.C. § 262(*l*)(1)(B)(i). The reference to "paragraph (2)" is to the provision at issue on this Conditional Cross-Petition, which requires the Applicant to give the Sponsor a copy of its aBLA and other information about the manufacture of its proposed biosimilar product within 20 days of being notified that the FDA has accepted its application for review:

> (2) Subsection (k) application information. Not later than 20 days after the [FDA] notifies the subsection (k) applicant that the application has been accepted for review, the subsection (k) applicant—
>
> (A) shall provide to the reference product sponsor a copy of the application submitted to the [FDA] under subsection (k), and such other information that describes the process or processes used to manufacture the biological product that is the subject of such application; and
>
> (B) may provide to the reference product sponsor additional information requested by or on behalf of the reference product sponsor.

42 U.S.C. § 262(*l*)(2)(A), (B) (emphasis added).

The Federal Circuit interpreted the verb "shall" in subparagraph 262(*l*)(2)(A) not to be mandatory, holding, over a dissent by Judge Newman, that the BPCIA explicitly contemplates that an Applicant need not provide the Sponsor with a copy of its aBLA and manufacturing information, and that where an Applicant refuses to provide this information the Sponsor's sole remedy is to sue for a declaratory judgment under 42 U.S.C. § 262(*l*)(9)(C) or for patent infringement under 35 U.S.C. § 271(e)(2)(C)(ii), limited to the remedies in 35 U.S.C. § 271(e)(4). (Pet. App. at 15a-18a.) The Court held that Sandoz's refusal to provide Amgen with a copy of Sandoz's aBLA and manufacturing information under subparagraph 262(*l*)(2)(A) was not a violation of the BPCIA sufficient to support an injunction under Amgen's California state-law claims. (Pet. App. at 27a-29a.)

The Federal Circuit reached this holding despite this Court's clear precedent that the verb "shall" ordinarily signifies a mandatory command, a meaning that is reinforced where—as here—the "shall" command is juxtaposed against the permissive "may." *See, e.g., Nat'l Ass'n of Home Builders v. Defenders of Wildlife*, 551 U.S. 644, 661-62 (2007); *Lopez v. Davis*, 531 U.S. 230, 241 (2001); *United States ex rel. Siegel v. Thoman*, 156 U.S. 353, 359-60 (1895). And by allowing the Applicant to refuse to provide its aBLA and manufacturing information, the Federal Circuit allowed the Applicant to prevent the later steps of the elaborate process that depend on the provision of that information, including paragraphs 262(*l*)(3), (4), and (5), and to prevent the filing of the "Immediate

patent infringement action" under paragraph 262(*l*)(6) that Congress intended to end the first phase of dispute resolution under the BPCIA. Here, too, Judge Newman dissented. (Pet. App. at 35a-42a.)

180 Days' Notice Under § 262(*l*)(8)(A): The second phase of dispute resolution begins when the FDA approves the Applicant's aBLA. *See* 42 U.S.C. § 262(*l*)(8). The statute requires the Applicant then to give at least 180 days' notice to the Sponsor of the date on which it will commence commercial marketing, in order to give the Sponsor time to bring, and the courts time to address, preliminary-injunction motions, including on patents that issue after the exchange of information leading to the paragraph 262(*l*)(6) lawsuit or were otherwise not listed for inclusion in that lawsuit. *See id.* § 262(*l*)(7), (8)(A), (8)(B). Thus, the statute provides that "The subsection (k) applicant shall provide notice to the reference product sponsor not later than 180 days before the date of the first commercial marketing of the biological product licensed under subsection (k)." *Id.* § 262(*l*)(8)(A).

The Federal Circuit unanimously held, based on Congress's unique use here of the phrase "the biological product licensed" and on the statutory context, that notice of commercial marketing is effective only if given after FDA approval. (Pet. App. at 19a-22a.) And the Federal Circuit then held, in this regard over a dissent by Judge Chen, that the word "shall" in subparagraph 262(*l*)(8)(A) is mandatory. (Pet. App. at 23a-26a.)

Sandoz's Petition challenges the Federal Circuit's unanimous holding that effective notice may be given only after FDA approval. (*See* Pet. at ii.) And while Sandoz gave notice after FDA approval, committing to wait 180 days from then to begin commercial marketing, Sandoz now challenges as error the Federal Circuit's continuation of an injunction pending appeal to prohibit Sandoz from beginning commercial marketing in the 180-day period when it promised not to do so anyway. (*See* Pet. at 31.)

For the reasons set forth in Amgen's brief in opposition to Sandoz's Petition, the Court should deny Sandoz's Petition. To date there have been only seven lawsuits involving a biosimilar applicant's submission of an abbreviated biologics license application ("aBLA") to the FDA. All are still pending, and they present questions not only of underlying patent-law issues—whether a given product infringes a given patent, and the like—but also questions about how the BPCIA patent-litigation procedures are to be construed and applied. The Federal Circuit will hear oral argument on April 4, 2016 in a case about the very provision Sandoz would have this Court construe. *See Amgen Inc. v. Apotex Inc.*, No. 2016-1308 (Fed. Cir. appeal docketed Dec. 11, 2015) (addressing whether notice under subparagraph 262(*l*)(8)(A) is mandatory for an Applicant that provides its aBLA under subparagraph 262(*l*)(2)(A)).

If, however, this Court grants Sandoz's Petition, it should grant this Conditional Cross-Petition as well, to review the Federal Circuit majority's conclusion that the Applicant does not need to do

what subparagraph 262(*l*)(2)(A) says it "shall" do: provide the Sponsor with a copy of its aBLA and related manufacturing information. The Court should take up both issues if it takes up either, for these reasons:

First, the issues are inextricably intertwined. Both provisions are triggered by the Applicant's choice to seek FDA licensure under the subsection (k) pathway, rather than the traditional approval pathway. *See* 42 U.S.C. § 262(*l*)(1). And both provisions say that the Applicant "shall" do certain tasks, *see id.* § 262(*l*)(2)(A), (8)(A), yet differently composed majorities of the Federal Circuit construed one "shall" as mandatory and one, in effect, as optional. (*See* Pet. App. at 15a, 23a.) The Court should consider the meaning of both provisions if it considers the meaning of either.

Second, the Federal Circuit majority's decision that the "shall" in subparagraph 262(*l*)(2)(A) is optional conflicts with controlling precedent from this Court, including cases holding the verb "shall" is ordinarily mandatory, and is clearly mandatory where, as here, it is juxtaposed with the verb "may." *See, e.g., Nat'l Ass'n of Home Builders*, 551 U.S. at 661-62; *Jama v. Immigration & Customs Enf't*, 543 U.S. 335, 346 (2005); *Lopez*, 531 U.S. at 241; *Anderson v. Yungkau*, 329 U.S. 482, 485 (1947); *Thoman*, 156 U.S. at 359-60. The Federal Circuit majority's conclusion is also at odds with the larger statutory text, which at least four times refers to provision of the aBLA and manufacturing information as "required," and twice refers to an Applicant's non-provision of that information as a "fail[ure]." *See* 42 U.S.C. § 262(*l*)(1)(B)(i), (*l*)(9)(A),

(*l*)(9)(C); 35 U.S.C. § 271(e)(2)(C)(ii). The Federal Circuit majority's conclusion that an Applicant may simply refuse to participate in the threshold step of the procedures of subsection 262(*l*) destroys the balance the BPCIA sought to create between innovation and price competition, tipping that balance in favor of the Applicant. So, too, does the Federal Circuit majority's conclusion that, where an Applicant refuses to provide the information required by subparagraph 262(*l*)(2)(A), the Sponsor's sole remedy is to commence a declaratory-judgment action under 42 U.S.C. § 262(*l*)(9)(C) and/or a patent-infringement action under 35 U.S.C. § 271(e)(2)(C)(ii), limited to the remedies set forth in § 271(e)(4).

If the Court grants Sandoz's Petition to review another aspect of subsection 262(*l*) that is triggered by the filing of a subsection (k) application, it should grant Amgen's Conditional Cross-Petition as well.

STATEMENT OF THE CASE

A. The Biologics Price Competition and Innovation Act of 2009

Congress enacted the BPCIA as part of the Patient Protection and Affordable Care Act, because it was "the sense of the Senate that a biosimilars pathway balancing innovation and consumer interests should be established." Pub. L. No. 111-148, § 7001(b). Its goal was to allow for the regulation and licensure of potentially-lower-cost biosimilar products, while protecting the value to society of innovators' patent rights.

Before the BPCIA was enacted, the FDA could approve a biologics license application only under the full biologics pathway of 42 U.S.C. § 262(a), with its usual requirement of three phases of clinical trials to prove that "the biological product that is the subject of the application is safe, pure, and potent." 42 U.S.C. § 262(a)(2)(C)(i)(I). An innovator of a new biological product was assured that, even apart from whatever patent protection it might have on that product, no other company could copy that biological product and obtain FDA approval without first undergoing the expense of the 262(a) pathway. The innovator's investment to create a clinical trial data package to support and maintain FDA licensure of the innovator's biologic product was thereby protected from use, without the innovator's permission, by or for the benefit of would-be competitors.

The BPCIA changed that. Congress created a new biosimilars approval pathway, codified in 42

U.S.C. § 262(k) and commonly called "the (k) pathway." It allows the FDA to approve a biologic product that is "highly similar" to a "reference product" that was itself previously approved under the traditional subsection 262(a) pathway. *See id.* § 262(i)(2), (k)(3). Thus, while innovators previously enjoyed permanent and exclusive rights to their clinical trial data and FDA license, and reference to an innovator's biological license could be made only with permission from the innovator, the BPCIA advanced the public's interest in price competition in part by diminishing these innovators' rights. It allowed an Applicant to "reference" the innovator's license, and to demonstrate that its proposed product is "highly similar" to the innovator's "reference product," *id.* § 262(i)(2), (k)(3), rather than incurring the costs of generating its own clinical data to demonstrate safety and efficacy. The BPCIA has no grandfather provision that would limit its applicability to only reference products licensed after the effective date of the legislation. *See id.* § 262(k).

On the other side of the balance, Congress protected the public's interest in innovation by establishing in subsection 262(*l*), "Patents," what the Federal Circuit aptly termed a "unique and elaborate process for information exchange between the biosimilar applicant and the [Sponsor] to resolve patent disputes." (Pet. App. at 6a.) The process begins when the Applicant files an aBLA seeking review under the subsection (k) pathway. *See* 42 *U.S.C.* § 262(*l*)(1)(B)(i).

The provision at issue on this Conditional Cross-Petition, paragraph 262(*l*)(2), states:

> (2) Subsection (k) application information. Not later than 20 days after the [FDA] notifies the subsection (k) applicant that the application has been accepted for review, the subsection (k) applicant—
>
> (A) shall provide to the reference product sponsor a copy of the application submitted to the [FDA] under subsection (k), and such other information that describes the process or processes used to manufacture the biological product that is the subject of such application; and
>
> (B) may provide to the reference product sponsor additional information requested by or on behalf of the reference product sponsor.

Id. § 262(*l*)(2). The Sponsor then uses the Applicant's aBLA and manufacturing information to identify patents that the Sponsor believes could be infringed by the making, using, selling, offering for sale, or importing of the Applicant's proposed biosimilar product. Paragraph 262(*l*)(3) requires the Sponsor to identify those patents, and requires the Applicant and the Sponsor to exchange detailed infringement and invalidity contentions and to address licensure under some or all of those patents, and requires the Applicant to state whether it will await the expiry of some or all of those patents before marketing its product. *See id.* § 262(*l*)(3)(A), (B), (C). If there remain patents in dispute, the Sponsor and Applicant work together to identify which of those patents will be included in an "Immediate patent infringement action" under paragraph 262(*l*)(6). *See id.* § 262(*l*)(4), (5), (6).

The reason that the lawsuit in paragraph 262(*l*)(6) is called an "immediate" patent infringement action is that it represents the conclusion of the first of two phases under subsection 262(*l*). The second phase begins with the FDA's approval of the Applicant's biosimilar application. *See id.* § 262(*l*)(8). Because the BPCIA permits the submission of a biosimilar application four years after approval of the reference product, *id.* § 262(k)(7)(B), but prohibits licensure of the biosimilar product until twelve years after that date, *id.* § 262(k)(7)(A), the two phases of litigation may be separated by a period of several years.

FDA licensure of the biosimilar product authorizes the Applicant to commercially market the biosimilar in the United States. *See id.* § 262(a)(1)(A). It also triggers the Applicant's obligation to give the Sponsor at least 180 days' advance notice of the date of the first commercial marketing of the licensed biosimilar product. *See id.* § 262(*l*)(8)(A). (This is the provision addressed by Sandoz's Petition.) This allows the Sponsor an opportunity to seek a preliminary injunction prior to the commercial marketing of the approved product, including on the patents identified in subparagraph 262(*l*)(8)(B).

The final part of subsection 262(*l*), paragraph 262(*l*)(9), is entitled "Limitation on declaratory judgment action." In this regard, the BPCIA borrows from the Hatch-Waxman Act (which provides for an abbreviated FDA approval pathway for small-molecule drugs, and patent-dispute-resolution provisions for applicants and sponsors of

such drugs)[1] and prohibits gaming the system by placing limits on any actions for declaratory judgments with respect to patents that do not make the list, pursuant to either paragraph 262(*l*)(4) or 262(*l*)(5), for the immediate patent infringement action under paragraph 262(*l*)(6), plus later-issued or -licensed patents under paragraph 262(*l*)(7). Assuming compliance with the BPCIA patent provisions, that limitation first ends when the Applicant gives the at-least-180-days' advance notice of first commercial marketing of the licensed biosimilar product. Thus, subparagraph 262(*l*)(9)(A) provides:

> (9) Limitation on declaratory judgment action
>
> (A) Subsection (k) application provided—If a subsection (k) applicant provides the application and information required under paragraph (2)(A), neither the reference product sponsor nor the subsection (k) applicant may, prior to the date notice is received under paragraph (8)(A), bring any action under section 2201 of title 28 for a declaration of infringement, validity, or enforceability of any patent that is described in clauses (i) and (ii) of paragraph (8)(B).

Deferring the availability of declaratory-judgment actions until the Applicant provides the

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[1] Drug and Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (codified at 21 U.S.C. § 355, 28 U.S.C. § 2201, and 35 U.S.C. §§ 156, 271, & 282).

notice of commercial marketing benefits both the Applicant and the Sponsor, for example by ensuring that both parties earnestly engage in the first phase of the BPCIA's patent-resolution process and providing clarity that the respective rights of the parties are and will be preserved. If the Applicant fails to complete an action, the limitation on declaratory-judgment actions is maintained with respect to the Applicant but not with respect to the Sponsor:

> (B) Subsequent failure to act by subsection (k) applicant—If a subsection (k) applicant fails to complete an action required of the subsection (k) applicant under paragraph (3)(B)(ii), paragraph (5), paragraph (6)(C)(i), paragraph (7), or paragraph (8)(A), the reference product sponsor, but not the subsection (k) applicant, may bring an action under section 2201 of title 28 for a declaration of infringement, validity, or enforceability of any patent included in the list described in paragraph (3)(A), including as provided under paragraph (7).
>
> (C) Subsection (k) application not provided—If a subsection (k) applicant fails to provide the application and information required under paragraph (2)(A), the reference product sponsor, but not the subsection (k) applicant, may bring an action under section 2201 of title 28 for a declaration of infringement, validity, or enforceability of any patent that claims the biological product or a use of the biological product.

Id. § 262(*l*)(9)(B), (C).

B. Factual Background

1. Sandoz's aBLA and its Initial Notice of Commercial Marketing

Amgen discovered, developed, and markets NEUPOGEN® (filgrastim), a genetically engineered biologic protein that stimulates the production of neutrophils, a type of white blood cell. (*See* Pet. App. at 4a, 57a; D. Ct. Dkt. No. 1 at ¶¶ 45-47.) NEUPOGEN® is used, for example, to protect against a condition known as neutropenia, a potentially fatal neutrophil deficiency, induced in cancer patients by chemotherapy. (D. Ct. Dkt. No. 1 at ¶¶ 45-47.) The advent of NEUPOGEN® profoundly changed the treatment of many forms of cancer by greatly reducing deaths from neutropenia.

Sandoz filed an aBLA under the subsection (k) pathway seeking FDA approval of a biosimilar filgrastim product, designating Amgen's NEUPOGEN® as the reference product. (Pet. App. at 8a.) The FDA notified Sandoz it had accepted that aBLA on July 7, 2014. (*Id.*) Later in July, Sandoz informed Amgen that it would not provide Amgen with its aBLA or manufacturing information under subparagraph 42 U.S.C. § 262(*l*)(2)(A), and—purporting to satisfy the notice requirement of subparagraph 262(*l*)(8)(A)—informed Amgen that it would begin commercial marketing immediately upon FDA licensure. (Pet. App. at 8a-9a.) Sandoz said it expected to receive an FDA license some six to twelve months later, in the first half of 2015. (Pet. App. at 8a.)

2. District Court Proceedings, FDA Approval of Sandoz's aBLA, and Sandoz's Second Notice of Commercial Marketing

In October 2014, Amgen sued Sandoz in the Northern District of California, asserting claims of conversion, unlawful competition under California Business & Professions Code § 17200 et seq., and infringement of U.S. Patent 6,162,427. (Pet. App. at 9a.) The district court had subject matter jurisdiction under 28 U.S.C. § 1332, as well as under 28 U.S.C. § 1331 and 1338(a) with respect to Amgen's patent claims and 28 U.S.C. §§ 1367 and 1338(b) with respect to Amgen's state-law claims. Both state-law claims rested on Sandoz's violations of the BPCIA: Amgen alleged that Sandoz had competed unlawfully and converted the value of Amgen's license for NEUPOGEN® by availing itself of the right to reference that license under the BPCIA while refusing to disclose its aBLA and manufacturing information to Amgen under subparagraph 262(*l*)(2)(A) and giving improper notice of commercial marketing under subparagraph § 262(*l*)(8)(A). (*See id.*) Sandoz counterclaimed for declaratory judgments that its reading of the BPCIA was correct. (*Id.*) Amgen sought a preliminary injunction, and the parties cross-moved for judgment on Amgen's state-law claims and Sandoz's counterclaims. (*Id.* at 9a-10a.)

While the motions were pending, on March 6, 2015 the FDA approved Sandoz's aBLA, licensing Sandoz to sell its biosimilar filgrastim product under the name ZARXIO®. (*Id.* at 8a-9a.) That same day, while maintaining that its July 2014 notice of commercial marketing had been operative,

Sandoz gave Amgen a "further" notice of commercial marketing under subparagraph 262(*l*)(8)(A). (*Id.*)

On March 19, 2015, the district court granted partial judgment to Sandoz, holding that (i) despite the use of the words "shall provide," the BPCIA allows an Applicant to refuse to provide its aBLA and manufacturing information; (ii) where an Applicant refuses to provide that information, the Sponsor may not obtain injunctive relief, restitution, or damages for that refusal, and is instead limited to seeking a declaratory judgment under subparagraph § 262(*l*)(9)(C); and, (iii) the Applicant may give notice of commercial marketing under subparagraph 262(*l*)(8)(A) before FDA approval, and thus that Sandoz's July 2014 notice was timely. (*Id.* at 10a.) The district court entered judgment against Amgen on its state law claims, and denied its motion for a preliminary injunction. (*Id.*) Proceedings on Amgen's patent claim were stayed, and Amgen timely appealed to the Federal Circuit. (*Id.* at 11a.)

3. The Federal Circuit Decision

Amgen sought an injunction pending appeal under Fed. R. App. P. 8(a) and the traditional four factors of the equitable test for such an injunction: likelihood of success on the merits, irreparable harm, a balance of hardships favoring the movant, and the public interest. (*See* Pet. App. at 31a; CAFC Dkt. No. 55.) Over Sandoz's opposition, the Federal Circuit entered an injunction pending appeal on May 5, 2015, enjoining Sandoz from marketing, selling, or offering for sale its ZARXIO® product until the court resolved the appeal. (*See*

Pet App. at 31a; CAFC Dkt. No. 83; Order, CAFC Dkt. No. 105 (granting the motion).)

On July 21, 2015, the Federal Circuit issued its decision on Amgen's appeal. (*See* Pet. App. at 1a.) The panel comprised Judges Lourie, Newman, and Chen, with Judge Lourie writing the majority opinion, joined in various parts by Judge Newman and Judge Chen. (*See id.* at 3a.)

Addressing subparagraph 262(*l*)(2)(A), the provision now at issue on this Conditional Cross-Petition, Judge Lourie, joined by Judge Chen, held that while that provision says that the Applicant "shall provide" a copy of its aBLA and related manufacturing information to the Sponsor, that requirement is not actually mandatory, and where an Applicant refuses to provide that information the Sponsor's only recourse is to commence a patent-infringement suit under 35 U.S.C. § 271(e)(2)(C)(ii) or a declaratory-judgment action under 42 U.S.C. § 262(*l*)(9)(C) and obtain that information through discovery. (*See id.* at 12a-18a.) Because it found that Sandoz had not violated the BPCIA, the majority affirmed the entry of judgment on Amgen's state-law claims to the extent they were predicated on Sandoz's refusal to provide its aBLA and manufacturing information. (*See id.* at 26a-29a.) Judge Newman dissented from these aspects of the majority's decision. (*See id.* at 35a-42a.)

Turning to the notice of commercial marketing under subparagraph 262(*l*)(8)(A), the Federal Circuit held, unanimously, that such notice is effective only if given after the FDA licenses the product under subsection (k). (*Id.* at 20a-22a.) The

court then considered Sandoz's argument that the "shall" language of subparagraph 262(*l*)(8)(A) is not mandatory and that an Applicant need not provide notice at all. (*Id.* at 23a-26a.) Judge Lourie, joined by Judge Newman, held that an Applicant must give notice of commercial marketing under subparagraph 262(*l*)(8)(A). (*Id.*) Deeming Sandoz's March 6, 2015 notice of commercial marketing to have been "operative and effective" (*id.* at 23a), the majority held that "Sandoz therefore may not market Zarxio before 180 days from March 6, 2015, *i.e.*, September 2, 2015" (*id.* at 26a), and extended the injunction pending appeal to only September 2, 2015 (*id.* at 27a-28a, 31a). The majority held that in light of this injunction, "Amgen's appeal from the dismissal of its unfair competition claim based on the alleged violation of § 262(*l*)(8)(A) is therefore moot." (*Id.*) Judge Chen dissented from these parts of the panel decision. (*See id.* at 42a-55a.)

Each of Sandoz and Amgen petitioned for en banc review, with Sandoz challenging aspects of the panel's decision regarding notice of commercial marketing under subparagraph 262(*l*)(8)(A) and Amgen challenging the panel's decision regarding the Applicant's obligation to give the Sponsor a copy of its aBLA and manufacturing information under subparagraph 262(*l*)(2)(A). (*See* CAFC Dkt. Nos. 118 & 119.) Both petitions for en banc review were denied without further opinion. (Pet. App. at 85a-86a.) Amgen sought to extend the injunction pending appeal while en banc proceedings continued, and that application, too, was denied. (CAFC Dkt. No. 128.) Sandoz began commercial

sales of its ZARXIO® product on September 3, 2015. (Pet. at 20.)

4. Proceedings in This Court

Sandoz filed a petition for a writ of certiorari, No. 15-1039, on February 16, 2016, which was docketed on February 18, 2016.

Sandoz's Petition challenges two aspects of the Federal Circuit's decision: (1) the unanimous holding that the notice of commercial marketing pursuant to 42 U.S.C. § 262(*l*)(8)(A) is effective only if given after FDA approval of the biosimilar, and not before; and (2) the extension of an injunction pending appeal through September 2, 2015, which was 180 days after Sandoz's March 6, 2015 notice of commercial marketing. For the reasons set forth in its brief in opposition, Amgen respectfully submits that the Court should deny Sandoz's petition for certiorari.

This Conditional Cross-Petition challenges the Federal Circuit's decision that the language in subparagraph 262(*l*)(2)(A) that the Applicant "shall provide" the Sponsor with a copy of its aBLA and manufacturing information is not mandatory, and that where an Applicant refuses to provide that information the Sponsor's only recourse is to commence a patent-infringement suit under 35 U.S.C. § 271(e)(2)(C)(ii) or a declaratory-judgment action under 42 U.S.C. § 262(*l*)(9)(C) and obtain that information through discovery.

If the Court denies Sandoz's Petition, it should deny Amgen's Conditional Cross-Petition as well. If

the Court grants Sandoz's Petition, however, then it should grant this Conditional Cross-Petition too.

REASONS FOR GRANTING THE CONDITIONAL CROSS-PETITION

I. THE COURT SHOULD REVIEW TOGETHER TWO COMPONENTS OF THE SAME INTEGRATED STATUTE, TO WHICH THE FEDERAL CIRCUIT ASSIGNED CONFLICTING MEANINGS DESPITE THEIR IDENTICAL RELEVANT LANGUAGE

Subparagraph 262(*l*)(2)(A) and subparagraph 262(*l*)(8)(A) are each triggered by the Applicant's decision to file an aBLA under the subsection (k) pathway, *see* 42 U.S.C. § 262(*l*)(1)(B)(i), thus availing itself of the Sponsor's clinical trial data package and license, rather than filing under the traditional subsection (a) pathway and needing to generate its own data package. *See generally id.* § 262(k). An Applicant that elects the subsection (k) pathway undertakes concomitant obligations under the patent-dispute-resolution regime of subsection 262(*l*) that protect the public's interest in promoting innovation by safeguarding patent rights. *See id.* § 262(*l*)(1)(B)(i), (*l*)(2)-(8).

Although the first physical act of the process is the provision of the Applicant's aBLA and manufacturing information to the Sponsor, *see* 42 U.S.C. § 262(*l*)(2)(A), the statute commits the Applicant to this process the moment the Applicant chooses the abbreviated regulatory pathway of subsection (k): "When a subsection (k) applicant submits an application under subsection (k), such

applicant shall provide to [the Sponsor] . . . confidential access to the information required to be produced pursuant to paragraph (2)." *See id.* § 262(*l*)(1)(B)(i). The information-exchange provisions of paragraphs 262(*l*)(3), (4), and (5) all depend on the Applicant providing its aBLA and manufacturing information under subparagraph 262(*l*)(2)(A), as does the Sponsor's commencement of the immediate patent infringement action under paragraph 262(*l*)(6), and as does the provision for supplementing the previous patent lists with newly-issued or -licensed patents under paragraph 262(*l*)(7). And the notice of commercial marketing required under subparagraph 262(*l*)(8)(A) also is triggered by the Applicant's having chosen the subsection (k) pathway rather than the traditional subsection (a) pathway.

All of these provisions speak in terms of what the Applicant (and, sometimes, the Sponsor) "shall" do. The provisions at issue on Sandoz's Petition and Amgen's Conditional Cross-Petition each state that the Applicant "shall" do something in the BPCIA's patent-dispute-resolution regime. *See* 42 U.S.C. § 262(*l*)(2)(A), (*l*)(8)(A). Yet the Federal Circuit assigned contradictory meanings to identical verbs, holding that one "shall" is mandatory and one is optional. (*Contrast* Pet. App. at 15a ("[S]hall in paragraph (*l*)(2)(A) does not mean 'must.'"), *with id.* at 23a ("A question exists, however, concerning whether the 'shall' provision in paragraph (*l*)(8)(A) is mandatory. We conclude that it is.").) If the Court construes either provision, it should construe both at the same time, and—consistent with the statute's text—construe them as mandatory.

It would cause great confusion to the lower courts and the biopharmaceutical industry if this Court were to decide the meaning of "shall" for only one provision of the statute and not for all of its provisions, or to decide that one "shall" is mandatory but others are not.

Moreover, the provisions of subsection 262(*l*) are connected not only in language but in function. On this, the parties agree. For its part, Sandoz asserts that which of the Applicant or the Sponsor can commence patent litigation, "when, and for what relief depends on the actions or inactions at each step of a multi-step information exchange process between the applicant and the sponsor regarding the sponsor's possible patent claims. 35 U.S.C. § 271(e)(2)(C), (4), (6); 28 U.S.C. § 2201(b); 42 U.S.C. § 262(*l*)(2)-(9)." (Pet. at 9.) Indeed, one of Sandoz's bases for seeking certiorari is its criticism that the Federal Circuit wrongly treated subparagraph 262(*l*)(8)(A) as a "standalone" provision, "disconnecting the notice provision from the BPCIA's patent resolution regime." (*Id.* at 22.) While that one subparagraph is not itself tied to any other provision of subsection 262(*l*), and thus while it does stand alone, Sandoz and Amgen agree that the provisions as a whole interrelate with each other in defining the obligations of the Applicant and the Sponsor where an Applicant chooses to avail itself of the subsection (k) pathway.

Therefore, if the Court is to address subparagraph 262(*l*)(8)(A) in Sandoz's Petition, it should address the statutory subsection as a whole, including the Federal Circuit's construction of subparagraph 262(*l*)(2)(A). As Amgen shows below

in Point II, that construction runs afoul of this *Court's statutory-construction precedents*, independently warranting review.

II. THE FEDERAL CIRCUIT'S CONSTRUCTION OF THE VERB "SHALL" IN SUBPARAGRAPH *262(L)(2)(A) CONFLICTS WITH THIS COURT'S* STATUTORY-INTERPRETATION *PRECEDENTS*

A. Congress's Use of "Shall" and "May" Confirms *That "Shall" Is Mandatory*

This Court's precedents instruct that "all statutory construction cases . . . begin with the language of the statute." *Barnhart v. Sigmon Coal Co.*, 534 U.S. 438, 450 (2002). Here, Congress used clear language to compel the Applicant to provide its *aBLA and manufacturing information to the* Sponsor:

> (2) Subsection (k) application information. Not later than 20 days after the [FDA] *notifies the subsection (k) applicant that the* application has been accepted for review, the subsection (k) applicant—
>
> (A) shall provide to the reference product *sponsor a copy of the application submitted* to the [FDA] under subsection (k), and such *other information that describes the process* or processes used to manufacture the biological product that is the subject of such application; and

> (B) may provide to the reference product sponsor additional information requested by or on behalf of the reference product sponsor.

42 U.S.C. § 262(*l*)(2) (emphasis added). The verb "shall," this Court instructs, is generally mandatory. *See, e.g., Nat'l Ass'n of Home Builders*, 551 U.S. at 661-62; *Lopez*, 531 U.S. at 241. And where—as here—"shall" is used in juxtaposition to the word "may," the "shall" is clearly mandatory. *See, e.g., Jama*, 543 U.S. at 346; *Lopez*, 531 U.S. at 241; *Anderson*, 329 U.S. at 485; *Thoman*, 156 U.S. at 359-60. The plain text of subparagraph 262(*l*)(2)(A) requires the Applicant to provide its aBLA and manufacturing information to the Sponsor.

B. The Surrounding Context Confirms That "Shall" Is Mandatory

While the language of subparagraph 262(*l*)(2)(A) is thus itself sufficient to confirm the Applicant's obligation to provide the aBLA and manufacturing information, the BPCIA reinforces this obligation in several other sections.

It does so first by tying an Applicant's choice to access the biosimilar subsection (k) pathway to its providing this information, stating that: "When a subsection (k) applicant submits an application under subsection (k), such applicant shall provide" to the Sponsor "the information required to be produced pursuant to paragraph (2)." 42 U.S.C. § 262(*l*)(1)(B)(i) (emphases added).

The use of the phrase "the information required

to be produced pursuant to paragraph (2)" is not unique to subparagraph 262(*l*)(1)(B)(i). The BPCIA refers to the aBLA and manufacturing information as "required" in three other places, in two of them referring to non-provision of that information as a "failure":

- Subparagraph 262(*l*)(9)(A) begins, "If a subsection (k) applicant provides the application and information required under paragraph (2)(A) . . . ." (emphasis added).

- Subparagraph 262(*l*)(9)(C) begins, "If a subsection (k) applicant fails to provide the application and information required under paragraph (2)(A) . . . ." (emphasis added).

- The provisions added to the Patent Act to create a technical act of infringement as part of the BPCIA state, in relevant part, "if the applicant for the application fails to provide the application and information required under section [262](*l*)(2)(A) of" subsection 262(*l*). 35 U.S.C. § 271(e)(2)(C)(ii) (emphasis added).

These provisions further confirm that the Applicant is required to provide its aBLA and manufacturing information to the Sponsor.

C. The Statutory Purpose Confirms That "Shall" Is Mandatory

The statutory purpose also confirms that the Applicant is required to provide its aBLA and manufacturing information to the Sponsor.

As Judge Newman explained in dissent, the BPCIA "ensure[s] that litigation surrounding relevant patents will be resolved expeditiously and prior to the launch of the biosimilar product, providing certainty to the applicant, the reference product manufacturer, and the public at large." (Pet. App. at 35a (emphasis removed).) Among those relevant patents are manufacturing patents, which are particularly important in protecting innovation in the area of biologics. Thus, while the provisions of the Hatch-Waxman statute dealing with patent disputes concerning generic drugs cover only patents on the chemical entity or methods of use, the BPCIA includes manufacturing patents, *see* 42 U.S.C. § 262(*l*)(3), and requires the Applicant to provide "information that describes the process or processes used to manufacture the biological product that is the subject of such application" so the Sponsor can assert those patents. *Id.* § 262(*l*)(2)(A). Without the Applicant's aBLA and manufacturing information, the Sponsor would likely have no way of knowing which, if any, of its manufacturing patents would be infringed by the Applicant's manufacturing processes; those processes are nearly always closely held secrets.

If an Applicant can refuse to provide the required information, it can tip the balance that the BPCIA was intended to create. As Judge Newman observed: "Subsection (k) and subsection (*l*) are components of an integrated framework; to enjoy the benefits of subsection (k), the biosimilar applicant is obligated to comply with subsection (*l*)." (Pet. App. at 40a.) "The consequences of the

majority's ruling are significant," because an Applicant that fails to provide the required information violates the "explicit balance of obligations and benefits" of the BPCIA. (*Id.*)

The risk is particularly acute with respect to the set of remedies Congress created for biosimilar lawsuits. Congress made the filing of an aBLA under the subsection (k) pathway an act of patent infringement, *see* 35 U.S.C. § 271(e)(2)(C), in a way that parallels the treatment of Abbreviated New Drug Applications in the provisions of the Hatch-Waxman Act, *see id.* § 271(e)(2)(A). And Congress created specific remedies for that technical act of infringement in biosimilar cases, including a mandatory permanent injunction:

> [T]he court shall order a permanent injunction prohibiting any infringement of the patent by the biological product involved in the infringement until a date which is not earlier than the date of the expiration of the patent that has been infringed under paragraph (2)(C), provided the patent is the subject of a final court decision, as defined in section 351(k)(6) of the Public Health Service Act, in an action for infringement of the patent under section 351(*l*)(6) of such Act, and the biological product has not yet been approved because of section 351(k)(7) of such Act.

35 U.S.C. § 271(e)(4)(D). Converting to the section numbers as codified, that provision creates a mandatory permanent injunction for infringement

determined in a paragraph 262(*l*)(6) list if the reference product is still within its statutory period of exclusivity under paragraph 262(k)(7). But if the Applicant does not provide its aBLA and manufacturing information under subparagraph 262(*l*)(2)(A), then there will never be a paragraph 262(*l*)(6) lawsuit. There may well be litigation between the Applicant and the Sponsor, but it will by definition not be a paragraph 262(*l*)(6) lawsuit. The Applicant will have deprived the Sponsor of the ability to get the mandatory injunction in 35 U.S.C. § 271(e)(4)(D), simply by refusing to provide information the statute says it "shall provide." That upending of the regulatory balance does violence to the statute and to Congress's intent.

To that end, the Congressional record for a prior, rejected piece of biosimilar legislation confirms that the as-enacted provision of subparagraph 262(*l*)(2)(A) is mandatory. As Judge Newman noted in dissent (*see* Pet. App. at 38a), a prior bill, then called H.R. 1427, explicitly included a discretionary, rather than mandatory, patent-exchange procedure. *See, e.g.*, H.R. 1427, 111th Cong. § 3(a)(2)(k)(18)(F) (2009). So did a prior bill in the Senate. *See* S. 623, 110th Cong. § 3(a)(2)(k)(17)(E) (2007) ("Nothing in this paragraph requires an applicant or a prospective applicant to invoke the [patent notification and exchange] procedures set forth in this paragraph."). Neither of these bills passed, however, and the version of the BPCIA that did pass Congress contained the "shall provide" language instead. *See also Chickasaw Nation v. United States*, 534 U.S. 84, 93 (2001) ("We ordinarily will not assume that Congress intended to enact

statutory language that it has earlier discarded in favor of other language." (internal quotation marks omitted)).

D. The Federal Circuit Majority Erred in Concluding That "Shall" "Does Not Mean 'Must'"

The Federal Circuit majority (here, Judges Lourie and Chen) initially reached the conclusion that, "read in isolation, the 'shall' provision in paragraph (*l*)(2)(A) appears to mean that a subsection (k) application is required to disclose its aBLA and manufacturing information to the RPS by the deadline specified in the statute." (Pet. App. at 14a.) The majority noted that the BPCIA refers to this information as "required," and focused "[p]articularly" on the language in subparagraph 262(*l*)(1)(B)(i) that provides that an Applicant that "chooses the abbreviated pathway for regulatory approval of its biosimilar product . . . is required to disclose its aBLA and manufacturing information to the RPS." (*Id.* at 14a-15a.) The majority further recognized that the juxtaposition of "shall" and "may" "would appear to indicate that 'shall' signals a requirement." (*Id.* at 15a.)

The majority nevertheless concluded, however, that because of "other provisions" of the BPICA, the "'shall' in paragraph (*l*)(2)(A) does not mean 'must.'" (*Id.*) Specifically, the majority focused on two provisions that the majority concluded, "explicitly contemplate[] that a subsection (k) applicant might fail to disclose the required information by the statutory deadline" and, it found "set[] forth the

consequences for such failure." (*Id.*) Those two provisions are 35 U.S.C. § 271(e)(2)(C)(ii) and 42 U.S.C. § 262(*l*)(9)(C).

Here, the Federal Circuit majority erred. Neither of those provisions provides a remedy for an Applicant's refusal, or purports to limit the available remedies when an Applicant refuses, to provide its aBLA and manufacturing information to the Sponsor.

1. A Declaratory Judgment Under Subparagraph 262(*l*)(9)(C) Is Neither Remedial Nor an Exclusive Remedy

Subparagraph 262(*l*)(9)(C) is part of the "Limitation on Declaratory Judgment Action" imposed by paragraph 262(*l*)(9). Just as the Hatch-Waxman Act contains provisions designed to prohibit gun-jumping through declaratory-judgment actions, the BPCIA contains a prohibition on declaratory-judgment actions designed to last through the first phase of litigation, from the time the Applicant provides its aBLA and manufacturing information to start the information-exchanges that lead to the paragraph 262(*l*)(6) immediate patent infringement action until the FDA approves the aBLA and the Applicant gives 180 days' notice of commercial marketing. Thus, subparagraph 262(*l*)(9)(A) provides:

> (A) Subsection (k) application provided—If a subsection (k) applicant provides the application and information required under paragraph (2)(A), neither the reference

> product sponsor nor the subsection (k) applicant may, prior to the date notice is received under paragraph (8)(A), bring any action under section 2201 of title 28 for a declaration of infringement, validity, or enforceability of any patent that is described in clauses (i) and (ii) of paragraph (8)(B).

42 U.S.C. § 262(*l*)(9)(A). This prohibition on declaratory judgments then persists even where an Applicant fails to comply with the various requirements of subsection 262(*l*), but is lifted for the Sponsor. Subparagraph 262(*l*)(9)(B) continues the declaratory-judgment ban against an Applicant that fails at a later stage of the process, while subparagraph 262(*l*)(9)(C) continues the declaratory-judgment ban against an Applicant that fails to provide its aBLA and manufacturing information:

> (B) Subsequent failure to act by subsection (k) applicant—If a subsection (k) applicant fails to complete an action required of the subsection (k) applicant under paragraph (3)(B)(ii), paragraph (5), paragraph (6)(C)(i), paragraph (7), or paragraph (8)(A), the reference product sponsor, but not the subsection (k) applicant, may bring an action under section 2201 of title 28 for a declaration of infringement, validity, or enforceability of any patent included in the list described in paragraph (3)(A), including as provided under paragraph (7).
>
> (C) Subsection (k) application not provided—If a subsection (k) applicant fails to provide

> the application and information required under paragraph (2)(A), the reference product sponsor, but not the subsection (k) applicant, may bring an action under section 2201 of title 28 for a declaration of infringement, validity, or enforceability of any patent that claims the biological product or a use of the biological product.

42 U.S.C. § 262(*l*)(9)(B), (C).

Nothing in this paragraph conditions a Sponsor's or the courts' ability to remediate an Applicant's non-compliance with subparagraph 262(*l*)(2)(A) on the Sponsor bringing a declaratory-judgment action. And nothing in this paragraph says that a declaratory-judgment action is a Sponsor's only choice where the Applicant "fails" to provide its aBLA and manufacturing information. All that this paragraph does is prohibit the non-compliant Applicant from bringing certain kinds of declaratory-judgment actions.

As Judge Newman stated, "subsection (*l*)(9)(C) prevents a non-compliant party from obtaining relief through a declaratory judgment action, while that prohibition is lifted as to the aggrieved party." (Pet. App. at 41a.) And its scope is quite limited: it refers to only patents reading on the biological product or its use, not to the important class of manufacturing patents. (*See id.* at 37a-38a; *accord id.* at 16a (majority opinion).) Nothing about the language of this section suggests that it was intended to permit an Applicant to "opt" not to provide its aBLA and manufacturing information, or

that a declaratory-judgment action is the Sponsor's sole remedy where the Applicant—to use the statutory verb and adjective—fails to provide that required information.

2. A Patent-Infringement Suit Under 35 U.S.C. § 271(e)(2)(C)(ii) Is Neither Remedial Nor an Exclusive Remedy

The Federal Circuit majority also cited the technical act of infringement in 35 U.S.C. § 271(e)(2)(C)(ii) as another remedy available to a Sponsor for an Applicant's failure to comply with subparagraph 262(*l*)(2)(A). That provision is also neither remedial nor an exclusive remedy, and is no basis to conclude that "shall" does not mean "must."

As noted above, the BCPIA amended the Patent Act to add a technical act of infringement for biosimilar applications. *See* 35 U.S.C. § 271(e)(2)(C). The act of patent infringement is the submission of the aBLA; which patents are deemed infringed depends on whether the Applicant provides its aBLA and manufacturing information to the Sponsor, and thus whether the Sponsor can use that information to identify applicable patents pursuant to paragraph 262(*l*)(3):

> It shall be an act of infringement to submit—
>
> . . . .
>
> (C)(i) with respect to a patent that is identified in the list of patents described in [42 U.S.C. § 262(*l*)(3)] (including as provided under [42 U.S.C. § 262(*l*)(7)]), an application seeking approval of a biological product, or
>
> (ii) if the applicant for the application fails to provide the application and information required under [42 U.S.C. § 262(*l*)(2)(A)] of such Act, an application seeking approval of a biological product for a patent that could be identified pursuant to [42 U.S.C. § 262(*l*)(3)(A)(i)],
>
> if the purpose of such submission is to obtain approval under such Act to engage in the commercial manufacture, use, or sale of a drug, veterinary biological product, or biological product claimed in a patent or the use of which is claimed in a patent before the expiration of such patent.

The Federal Circuit majority held that "[u]nder § 271(e)(2)(C)(ii), filing a subsection (k) application and failing to provide the required information under paragraph (*l*)(2)(A) is . . . an act of infringement" (Pet. App. at 16a), and thus that 35 U.S.C. § 271(e)(4) sets forth "the only remedies which may be granted by a court for" that "act of infringement," which do not include an injunction

by the Sponsor to compel statutory compliance (*id* at 18a (emphasis removed)).

That was error. Failing to provide the aBLA and manufacturing information is not an act of infringement. The act of infringement is the submission of the aBLA to the FDA: "It shall be an act of infringement to submit . . . an application seeking approval of a biological product." 35 U.S.C. § 271(e)(2)(C)(ii). The majority reads a limitation into infringement under section 271(e)(2)(C)(ii) that is inconsistent with sections 271(e)(2)(A), (B), and (C)(i)—all of which state that the submission of an application alone shall be an act of infringement. Providing or failing to provide the aBLA and manufacturing information determines the scope of infringement, specifically which patents have been infringed. If the Applicant complies with subparagraph 262(*l*)(2)(A), then submitting its aBLA infringes only the patents identified through exchange in paragraph 262(*l*)(3). If the Applicant fails to provide its aBLA and manufacturing information, then submitting its aBLA infringes any patent that could be identified by the Sponsor during the patent-dispute-resolution regime. Regardless of which patents have been infringed, the remedies provided under section 271(e)(4) are remedies for that infringement and not for a failure to provide the information required under subparagraph 262(*l*)(2)(A).

Where an Applicant fails to provide that information, the Sponsor may sue for patent infringement. But nothing in the BPCIA makes suing for patent infringement the only remedy

available. Indeed, nothing in the BPCIA makes the requirements of 42 U.S.C. § 262(*l*)(2)(A) depend upon the Sponsor's ownership of or license to patents at all.

* * * *

The Federal Circuit majority erred in suggesting that mandating compliance with subparagraph 262(*l*)(2)(A) "would render paragraph (*l*)(9)(C) and 35 U.S.C. § 271(e)(2)(C)(ii) superfluous." (Pet. App. at 17a.) They are not superfluous. They are among the tools available to a Sponsor where an Applicant refuses to comply with the BPCIA. But nothing about the value of those tools would be undermined by permitting, and nothing about the text or existence of those tools prevents, Sponsors and courts from using broad powers under federal and state laws to remediate the harms to these or, for example, other property rights caused by an Applicant's failure to comply with the BPCIA.

Those harms are not limited to patent infringement. Applicant non-compliance affects the value of innovation, the value of a Sponsor's biologics license, and the value to the court system of an orderly, targeted dispute-resolution regime, and it permits an Applicant to benefit from the subsection 262(k) pathway while denying the Sponsor its rights under subsection 262(*l*). The Federal Circuit majority's decision diminishes the property interest of an innovator like Amgen—which made substantial, risk-based investments, prior to the enactment of the BPCIA, to create a

clinical trial data package and secure and maintain an FDA license for the reference product—by allowing the Applicant to reference that FDA license and clinical trial data without fulfilling its own obligations under the BPCIA and without any means for the Sponsor to compel it to do so. As Judge Newman concluded in dissent, "It is not denied that Sandoz obtained the benefit of the Amgen data in filing under subsection (k). Sandoz should be required to respect its obligations, in fidelity to the statute." (*Id.* at 42a.)

If this Court accepts Sandoz's Petition to review the timing of the obligation in subparagraph 262(*l*)(8)(A) that an Applicant "shall provide" 180 days' notice of commercial marketing, this Court should therefore also grant this Conditional Cross-Petition to review the Federal Circuit's conclusion that in subparagraph 262(*l*)(2)(A) the word "shall" "does not mean 'must'" (*id.* at 15a), and that a Sponsor's sole remedy in the face of Applicant non-compliance is to commence a declaratory-judgment action under 42 U.S.C. § 262(*l*)(9)(C) and/or a patent-infringement action under 35 U.S.C. § 271(e)(2)(C)(ii), limited to the remedies in § 271(e)(4). That conclusion is at odds with the Federal Circuit's own treatment of the same word, "shall," in subparagraph 262(*l*)(8)(A), it is at odds with the plain words of the statute, its statutory context, its statutory purpose, and it conflicts with this Court's controlling statutory-construction precedents.

CONCLUSION

This Court should deny Sandoz's Petition in No. 15-1039 for the reasons set forth in Amgen's brief in opposition. But if this Court grants Sandoz's Petition, it should also grant Amgen's Conditional Cross-Petition.

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In The

Supreme Court of the United States

AMGEN INC. AND AMGEN MANUFACTURING LIMITED, CROSS-PETITIONERS,

v.

SANDOZ INC.

ON CROSS-PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

OPPOSITION TO THE CONDITIONAL CROSS-PETITION FOR A WRIT OF CERTIORARI

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QUESTION PRESENTED

In the Biologics Price Competition and Innovation Act of 2009 ("BPCIA"), Congress created an abbreviated regulatory pathway for the Food and Drug Administration ("FDA") to license "biosimilar" products—i.e., products that are "highly similar" to approved biological products. 42 U.S.C. § 262(i)(2). The BPCIA also created a carefully reticulated patent resolution regime for biosimilar applicants and the incumbent sellers of biological products, called reference product sponsors. As part of that regime, the statute provides that, within 20 days of the FDA's acceptance of a biosimilar application, the applicant "shall provide" a copy of the application to the reference product sponsor as the first step in a patent exchange and resolution scheme. *Id.* § 262(*l*)(2)(A). The BPCIA also expressly lays out a separate path for resolving any patent disputes in the event the applicant does not take that step: patent infringement litigation, with the scope and timing at the sole discretion of the sponsor. *Id.* § 262(*l*)(9)(C); 35 U.S.C. § 271(e)(2)(C)(ii).

The question presented is:

When a biosimilar applicant does not provide its application to the reference product sponsor under 42 U.S.C. § 262(*l*)(2)(A), can the sponsor obtain an injunction under California law requiring the applicant to do so?

RULE 29.6 CORPORATE DISCLOSURE STATEMENT

Pursuant to Rule 29.6, cross-respondent Sandoz Inc. states the following:

Sandoz Inc. is an indirect, wholly owned subsidiary of Novartis AG, which trades on the SIX Swiss Exchange under the ticker symbol NOVN and whose American Depository Shares are publicly traded on the New York Stock Exchange under the ticker symbol NVS.

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INTRODUCTION

For Amgen to succeed on the state law claims at issue in its conditional cross-petition, Amgen would have to establish that the Federal Circuit erred *both* in its interpretation of the federal BPCIA statute *and* in its conclusions that Amgen's claims failed for separate reasons of California law. Amgen can establish neither. The court of appeals correctly concluded that (1) the BPCIA does not require a biosimilar applicant to disclose its application to the sponsor in all circumstances, and thus Amgen cannot establish the "unlawful" element of its state law claims, *and* (2) Amgen also failed to satisfy all the other required California law elements. The independent state law grounds make Amgen's conditional cross-petition a poor vehicle for review of the proper interpretation of the BPCIA's disclosure provisions. In contrast to the questions presented by Sandoz's petition—which challenge the Federal Circuit's creation of a *federal* injunctive remedy directly under the BPCIA to enforce its notice of commercial marketing provision—the cross-petition's arguments could support at most an advisory opinion on the meaning of the BPCIA's disclosure provisions, unless this Court were to take the unusual step of reaching questions of state law. For these reasons, the portion of the judgment challenged by Amgen does not warrant this Court's review.

As explained more fully in Sandoz's petition for a writ of certiorari, the BPCIA's patent exchange process includes a series of steps that an applicant or sponsor

"shall" take to start or continue the patent exchange process and a linked series of consequences that follow from not doing so. Amgen's conditional cross-petition involves the first such step: an applicant "shall provide" a copy of its biosimilar application to the sponsor within 20 days after the FDA accepts the application for review. 42 U.S.C. § 262(*l*)(2)(A). If the applicant does not do so, the BPCIA expressly lays out a separate path for resolving any patent disputes: patent infringement litigation, with the scope and timing at the sole discretion of the reference product sponsor. *Id.* § 262(*l*)(9)(C); 35 U.S.C. § 271(e)(2)(C)(ii).

Sandoz chose not to provide its biosimilar application and instead to subject itself to the risk of immediate patent litigation. In response, Amgen filed suit, asserting (as relevant here) that Sandoz's decision to withhold its application was "unlawful" under the BPCIA. But in making these allegations, Amgen did not invoke any cause of action under the BPCIA itself or claim any right to an injunction under that federal statute. Instead, Amgen brought state law claims, alleging that Sandoz's alleged violations of the BPCIA provided bases for state law injunctive remedies under (1) California's Unfair Competition Law ("UCL"), Cal. Bus. & Prof. Code § 17200 *et seq.*, and (2) the common law of conversion.

The Federal Circuit rejected Amgen's state law claims relating to disclosure of the biosimilar application, for two independent reasons. ***First***, the court of appeals correctly interpreted the relevant portion of

the BPCIA. It held that the BPCIA expressly contemplates that an applicant may choose to withhold its application and that the statute lays out a specific path for resolution of any patent disputes in that situation. Correctly recognizing that there is nothing "unlawful" about taking an option provided by a statute, the court of appeals held that Sandoz did not act unlawfully by withholding its application. And because unlawful action was a required element of each of Amgen's California causes of action, both claims failed on that basis.

Second, the court of appeals also correctly held that each claim failed for independent state law reasons: the California UCL claim because that statute provides no remedy for alleged violations of schemes that make their own remedies expressly exclusive, and the California conversion claim because Amgen did not establish an exclusive right to its approved license. Amgen's conditional cross-petition thus presents a singularly poor vehicle for review. To obtain reversal of the Federal Circuit's judgment, Amgen would have to persuade this Court not only that the court of appeals' interpretation of the BPCIA was wrong (which Amgen cannot do), but *also* that the court's interpretation of separate elements of California UCL and conversion law was erroneous. This Court does not typically grant certiorari to resolve state law questions, and Amgen does not even attempt to explain why the Court should take that extraordinary step here.

By contrast, the portion of the Federal Circuit's judgment challenged by Sandoz's certiorari petition

presents none of these complications. The court of appeals held that Amgen has a *federal* cause of action to enforce the court of appeals' interpretation of the BPCIA's notice of commercial marketing provision by means of a *federal* injunctive remedy—which the Federal Circuit issued. Sandoz's petition thus asks this Court to review the grant of a federal remedy for what the Federal Circuit held to be a violation of federal law.

Amgen is therefore wrong in asserting that if the Court grants Sandoz's petition it also should grant Amgen's conditional cross-petition. Each petition must meet this Court's certiorari standards on its own, and Amgen's does not. Moreover, Amgen's choice to file only a conditional cross-petition—as well as the lack of any amici supporting it—suggests its question presented is not sufficiently important to warrant this Court's consideration.

The conditional cross-petition should be denied.

JURISDICTION

The judgment of the court of appeals was entered on July 21, 2015, not July 1, 2015, as stated in the conditional cross-petition. Sandoz is otherwise satisfied with the statement of jurisdiction in the conditional cross-petition.

STATEMENT

A. Statutory Background

Sandoz's petition includes a detailed description of the BPCIA, which will not be repeated in full here. 15-1039 Pet. 8-11. Amgen's conditional cross-petition

involves the first step of the BPCIA's patent exchange process, in which the applicant "shall provide" a copy of its biosimilar application to the sponsor within 20 days after the FDA accepts the application for review. 42 U.S.C. § 262(*l*)(2)(A). Throughout the BPCIA, Congress spelled out the actions the applicant or sponsor "shall" take to start and continue the process. In later steps, the parties exchange lists of patents for which they believe a claim of patent infringement could reasonably be asserted; exchange their respective positions on infringement, validity, and enforceability; and negotiate regarding the patents for which an immediate infringement action may be brought. *Id.* § 262(*l*)(3)-(5).

Congress also spelled out exactly what happens if a party declines to follow a particular step in the information exchange process. As particularly relevant here, if the applicant does not take the first step (i.e., provide its biosimilar application to the sponsor within 20 days of its acceptance by the FDA), the BPCIA expressly lays out a separate path for resolving any patent disputes: patent litigation, with the scope and timing at the sole discretion of the reference product sponsor. *Id.* § 262(*l*)(9)(C); 35 U.S.C. § 271(e)(2)(C)(ii). Even if the patent exchange process is initiated, and regardless of whether it is completed, the end result is that the reference product sponsor or the applicant can bring a patent suit. The contours of that suit are determined by the actions that the parties did or did not take in the information exchange process. 35 U.S.C. § 271(e)(2)(C), (4), (6); 42 U.S.C. § 262(*l*)(6), (9)(A)-(B).

B. Factual Background

1. Sandoz's biosimilar application

On July 7, 2014, the FDA accepted for review Sandoz's application for biosimilar filgrastim. Pet. App. 8a.[1] The next day, Sandoz notified Amgen that Sandoz had filed the application and that Sandoz expected FDA approval in the first half of 2015. *Ibid.*

In light of Amgen's public statements in filings with the Securities and Exchange Commission that it had no material, unexpired patents for filgrastim, Sandoz determined that subjecting itself to an immediate patent suit was the quickest path to resolution of any patent claims. CA JA A915, A960, A1495-A1497. On July 25, 2014, Sandoz therefore informed Amgen that it had "opted not to provide Amgen with Sandoz's biosimilar application within 20 days of the FDA's notification of acceptance" and that the BPCIA thus entitled Amgen to bring a declaratory judgment action for patent infringement against Sandoz. Pet. App. 8a; *see* 42 U.S.C. § 262(*l*)(9)(C). Amgen thus had the ability to sue to enforce any patent rights months earlier than would have been the case if Sandoz had participated in the patent exchange process, which "could take up to 230 days." Pet. App. 72a.

2. Proceedings in district court

a. Although Amgen could have brought a declaratory judgment action for artificial infringement as

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[1] All appendix citations are to the petition appendix in No. 15-1039.

early as July 28, 2014, it delayed bringing suit until October 2014, when it asserted three claims. Pet. App. 9a.

First, Amgen brought a claim under California's UCL statute, which provides a cause of action against "any unlawful, unfair or fraudulent business act or practice." Pet. App. 26a. Amgen alleged that Sandoz committed "unlawful" acts for purposes of the UCL by violating the BPCIA. Pet. App. 9a. As relevant to Amgen's conditional cross-petition, Amgen alleged that Sandoz violated the BPCIA by not providing Amgen its application within 20 days of the FDA's acceptance of Sandoz's application. *Ibid.* Amgen also alleged that Sandoz acted unlawfully by giving an allegedly premature, ineffective notice of commercial marketing before FDA approval, *ibid.*—the claim at issue in Sandoz's petition for a writ of certiorari. *See* 42 U.S.C. § 262(*l*)(8)(A).

Second, Amgen brought a state law claim for conversion, alleging that Sandoz wrongfully used Amgen's approved license for Neupogen® without complying with the BPCIA. Pet. App. 9a.

Third, expressly invoking the recourse provided by the BPCIA, 42 U.S.C. § 262(*l*)(9)(C), Amgen brought a claim for artificial infringement of Amgen's U.S. Patent No. 6,162,427 ("'427 patent"), which claims a method of treating a patient using filgrastim. Pet. App. 9a; *see* 15-1039 Pet. 9 (discussing BPCIA's creation of artificial acts of infringement to promote early resolution of patent disputes). Amgen, however, did not seek (and

still has not sought) an injunction based on purported patent infringement.

Sandoz counterclaimed, seeking declaratory judgments concerning the correct interpretation of the BPCIA in order to "resolve Amgen's claims for conversion and violation of California's Unfair Competition Law," and declaratory judgments for non-infringement and invalidity of the '427 patent. Pet. App. 9a; *see* CA JA A281.

b. On March 6, 2015, the FDA approved Sandoz's biosimilar filgrastim product Zarxio®, the first biosimilar approved under the BPCIA. Pet. App. 8a-9a. Sandoz provided Amgen a "further notice of commercial marketing" on that same day. Pet. App. 9a.

c. Later in March 2015, the district court denied Amgen's motions for judgment on the pleadings and for a preliminary injunction and granted Sandoz's motion for judgment on Amgen's state law claims and Sandoz's BPCIA counterclaims. Pet. App. 56a-84a.

The district court concluded that it was lawful for Sandoz not to provide Amgen its biosimilar application within 20 days of acceptance by the FDA. Pet. App. 68a-73a. The court noted that Section 262(*l*)(2)(A) states that an applicant "shall provide" a copy of its application to the reference product sponsor and that the patent exchange provisions often "use the word 'shall' to describe the parties' obligations under [subsection (*l*)'s] prescribed procedures." Pet. App. 69a. In context, however, the court explained that these provisions "demand that, if both parties wish to take

advantage of [the BPCIA's] disclosure procedures, then they 'shall' follow the prescribed procedures." *Ibid.* At the same time, the statute "contemplate[s] the scenario in which an applicant does not comply at all with disclosure procedures" by "allow[ing] the reference product sponsor to commence patent litigation immediately." Pet. App. 69a-70a.

The district court noted that Congress did not "remain silent" on remedies: "it expressly directed reference product sponsors to commence patent infringement litigation in the event of an applicant's noncompliance." Pet. App. 71a. "It is therefore evident that Congress intended merely to encourage use of the statute's dispute resolution process in favor of litigation, where practicable, with the carrot of a safe harbor for applicants who otherwise would remain vulnerable to suit." *Ibid.* The court observed that the statute "contains no stick to force compliance in all instances" and that "Amgen does not identify any basis to impute one." *Ibid.* "The effect of Amgen's position—that Congress intended for sponsors to resort to state laws to enforce mandatory provisions in a federal statute and collect remedies for their violation, in addition to exacting the consequences written expressly into the legislation itself—is unworkable." Pet. App. 78a-79a.[2]

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[2] The district court also concluded that it was lawful for Sandoz to provide its 180-day notice of commercial marketing before FDA approval, meaning that Sandoz's July 2014 notice was effective. Pet. App. 73a-76a. That issue is presented in Sandoz's petition for a writ of certiorari.

d. The district court entered final judgment under Federal Rule of Civil Procedure 54(b) on Amgen's state law claims and Sandoz's BPCIA counterclaims. Pet. App. 11a. The court granted the parties' joint request to stay all other proceedings, including Amgen's patent infringement claim and Sandoz's patent counterclaims. *Ibid.*

3. Proceedings in the Federal Circuit

a. In May 2015, the Federal Circuit issued an injunction pending appeal, precluding Sandoz from marketing, selling, offering for sale, or importing into the United States its FDA-approved Zarxio® product. Pet. App. 31a; CAFC Dkt. No. 105.

b. In July 2015, a fractured Federal Circuit panel affirmed the dismissal of Amgen's state law claims for unfair competition and conversion, vacated the judgment on Sandoz's counterclaims, and remanded. Pet. App. 1a-55a. The court also extended the injunction pending appeal through September 2, 2015—180 days from when the FDA approved Sandoz's filgrastim and Sandoz provided its second notice of commercial marketing. Pet. App. 31a.

On the issue raised by Amgen's cross-petition, a majority of the court (Judge Lourie joined by Judge Chen) held that Sandoz "did not violate the BPCIA by not disclosing its [application] and the manufacturing information by the statutory deadline" because in doing so Sandoz "took a path expressly contemplated by the BPCIA." Pet. App. 18a; *see also* Pet. App. 15a (noting that "the 'shall' provision in paragraph (*l*)(2)(A)

cannot be read in isolation"). As the court explained, the BPCIA "specifically sets forth the consequence for such failure" to provide the application: the sponsor "may bring an infringement action under 42 U.S.C. § 262(*l*)(9)(C) and 35 U.S.C. § 271(e)(2)(C)(ii)," but the applicant remains barred from bring its own declaratory judgment action. Pet. App. 15a-17a.

Indeed, the court of appeals observed that withholding the application and information "is precisely an act of infringement under § 271(e)(2)(C)(ii), for which § 271(e)(4) provides the 'only remedies.'" Pet. App. 18a. The statute "has no other provision that grants a procedural right to compel compliance with the disclosure requirement of paragraph (*l*)(2)(A)." Pet. App. 15a-16a. Both provisions triggered by an applicant's failure to disclose its application "are premised on a claim of patent infringement, and the BPCIA does not specify any non-patent-based remedies for a failure to comply with paragraph (*l*)(2)(A)." Pet. App. 17a.

The court of appeals noted that Amgen's UCL claim was "based solely" on that statute's "'unlawful' prong, which requires a showing that Sandoz acted unlawfully by violating another law, here, according to Amgen, the BPCIA." Pet. App. 26a-27a. The claim failed because, as the court had held, "Sandoz did not violate the BPCIA by not disclosing its [application] and the manufacturing information according to § 262(*l*)(2)(A)." Pet. App. 27a.

The court also explained that "[u]nder California law, UCL remedies are not available when the underlying law expressly provides that the remedies in that law are exclusive." Pet. App. 27a (citing Cal. Bus. & Prof. Code § 17205; *Loeffler v. Target Corp.*, 324 P.3d 50, 76 (Cal. 2014)). The court held that Amgen's claim failed for this reason as well: "35 U.S.C. § 271(e)(4) provides 'the only remedies which may be granted by a court' for the alleged violation" of withholding an application. Pet. App. 27a; *accord* Sandoz CA Br. 54-56.

The court likewise held that Amgen's conversion claim failed on two independent grounds—one based on the BPCIA and one based on state law. Pet. App. 28a-29a. First, because "the BPCIA explicitly contemplates that a subjection (k) applicant might not disclose its [application] and the manufacturing information by the statutory deadline, and provides that the [sponsor] may sue for patent infringement, which Amgen has done, Amgen thus failed to show a 'wrongful act,'" as required by the conversion cause of action. *Ibid.* Second, given the expiration of Amgen's period of exclusivity under the BPCIA, Amgen "fail[ed] to show that it has an *exclusive* right to possession of its approved license on Neupogen to sustain its claim of conversion under California law." Pet. App. 29a; *accord* Sandoz CA Br. 57.

Judge Newman dissented from this part of the decision. Pet. App. 35a-42a (Newman, J., dissenting).[3]

c. Sandoz launched its biosimilar filgrastim product Zarxio® in the United States on September 3, 2015.

d. Both Sandoz and Amgen filed petitions for rehearing en banc. Pet. App. 85a-86a. Sandoz's rehearing petition (addressing the notice of commercial marketing provision that is the subject of Sandoz's petition for a writ of certiorari) was supported by multiple amici stressing the importance of that issue: The Biosimilars Council (CAFC Dkt. No. 139), Hospira, Inc., Celltrion Healthcare Co., Ltd., and Celltrion, Inc. (CAFC Dkt. No. 140); and Mylan Inc. (CAFC Dkt. No. 150). Amgen's rehearing petition (addressing the application disclosure issue that is the subject of Amgen's conditional cross-petition) drew no amicus support. The Federal Circuit denied both petitions for en banc review. Pet. App. 85a-86a.

e. The Federal Circuit remanded to the district court, which lifted the stay on Amgen's patent claims

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[3] The Federal Circuit also interpreted the BPCIA's "[n]otice of commercial marketing" provision to mean that the "applicant may only give effective notice of commercial marketing *after* the FDA has licensed its product." Pet. App. 20a (emphasis added). The court further ruled that this interpretation could be enforced by issuance of an injunction under federal law, and barred Sandoz from marketing its biosimilar "before 180 days from March 6, 2015." Pet. App. 26a; *see* Pet. App. 31a. Those portions of the Federal Circuit's judgment are at issue in Sandoz's petition for a writ of certiorari.

and Sandoz's patent counterclaims. Amgen still has sought no patent-based injunction.

REASONS FOR DENYING THE CONDITIONAL CROSS-PETITION

The court of appeals concluded both that Sandoz did not violate the BPCIA by withholding its application and that Amgen's UCL and conversion claims failed for independent state law reasons. Those determinations do not warrant this Court's review. The Federal Circuit's interpretation of the BPCIA provisions challenged by Amgen was correct, and the necessity of resolving state law questions to reverse that portion of the judgment makes the conditional cross-petition a poor vehicle for review.

A. The Court Of Appeals Correctly Affirmed Dismissal Of Amgen's State Law UCL And Conversion Claims Because It Was Lawful For Sandoz Not To Provide Its Application Under Section 262(*l*)(2)(A)

The court of appeals correctly affirmed dismissal of Amgen's California UCL and conversion claims. Both claims require as one element that Sandoz have acted unlawfully when it withheld its application from Amgen. Pet. App. 26a-27a, 28a-29a. The court of appeals correctly held that Amgen could not satisfy this element. There was nothing unlawful in Sandoz's electing to take a path expressly laid out by the BPCIA.

1. The BPCIA's carefully reticulated regime expressly contemplates the patent resolution path taken by Sandoz

The Federal Circuit correctly concluded that "Sandoz did not violate the BPCIA by not disclosing its [application] and the manufacturing information according to § 262(*l*)(2)(A)." Pet. App. 27a. "Sandoz took a path expressly contemplated" by the BPCIA: withholding its application and subjecting itself to patent litigation at a time and scope of the sponsor's choosing—a suit that Amgen already has brought. *Ibid.*

The BPCIA created a carefully reticulated regime to allow patent disputes to commence before FDA approval, facilitating their resolution as quickly as possible. One route to the pre-approval patent infringement action created by the BPCIA is to complete the statutory patent exchange process. As a condition precedent to starting the process, the applicant "shall provide to the reference product sponsor a copy of the application submitted" within 20 days of the FDA's acceptance of the application. 42 U.S.C. § 262(*l*)(2)(A). But as the court of appeals recognized (Pet. App. 15a-18a), the BPCIA expressly contemplates that an applicant might not provide its application under subsection (*l*)(2)(A). *See* 42 U.S.C. § 262(*l*)(9)(C). In that event, the patent exchange process does not happen, and the BPCIA authorizes the sponsor to file suit immediately based on that act of artificial infringement, as Amgen has done. *See* 35 U.S.C. § 271(e)(2)(C)(ii); 42 U.S.C. § 262(*l*)(9)(C). As the Federal Circuit explained, "[o]nce the [sponsor] brings an infringement suit under

those two provisions, it can access the required information through discovery," as Amgen also has done. Pet. App. 17a.

Rather than allowing either party to compel compliance with any particular step in the patent exchange process, the BPCIA provides both parties incentives to participate. *See* Pet. App. 71a. The applicant that does not trigger the patent exchange process loses its ability to impact the timing of an artificial infringement suit by the sponsor, 42 U.S.C. § 262(*l*)(9)(A), and it loses the control it otherwise would have over which patents, or how many, the sponsor can assert. *Compare id.* § 262(*l*)(9)(C), *with id.* § 262(*l*)(3)-(5). Where the patent exchange process has not been triggered, the sponsor also decides whether to delay suit until after FDA approval, forcing the applicant to launch at risk. An applicant may nevertheless choose this path if the applicant seeks a quick resolution, believes that no unexpired, relevant patents will remain after the exclusivity period expires, and/or has concerns about turning over its application without a court protective order. *See* Pet. App. 72a.

In light of the BPCIA's integrated patent resolution regime, the court of appeals correctly concluded that "the 'shall' provision in paragraph (*l*)(2)(A) cannot be read in isolation." Pet. App. 15a. Despite many instances of "shall," the BPCIA provides multiple points at which the sponsor or the applicant may exit the patent exchange process, and the statute delineates the effect of that choice on the scope and timing of a patent suit. In particular, as the court of appeals correctly

concluded, the statute "specifically sets forth the consequence" when an applicant does not provide its application under subsection (*l*)(2)(A): "the [sponsor] may bring an infringement action under 42 U.S.C. § 262(*l*)(9)(C) and 35 U.S.C. § 271(e)(2)(C)(ii)." Pet. App. 15a. Those provisions "indicate that 'shall' in paragraph (*l*)(2)(A) does not mean 'must'" in all circumstances. *Ibid.* And "mandating compliance with paragraph (*l*)(2)(A) in all circumstances would render paragraph (*l*)(9)(C) and 35 U.S.C. § 271(e)(2)(C)(ii) superfluous." Pet. App. 17a. The court of appeals correctly concluded that taking "a path expressly contemplated by the BPCIA" cannot violate the Act. Pet. App. 18a.

Accordingly, the court of appeals concluded that Sandoz's withholding of its application was lawful under the BPCIA and therefore could not be the basis for a UCL or conversion cause of action. Pet. App. 27a (UCL), 28a-29a (conversion).

2. *None of Amgen's objections to the court of appeals' analysis has merit*

All of Amgen's criticisms of the court of appeals' analysis fail.

a. Amgen's principal submission is that the "plain text of subparagraph 262(*l*)(2)(A) requires the [a]pplicant to provide its [application] and manufacturing information to the [s]ponsor" because that provision uses the word "shall," which is "generally mandatory." Cross-Pet. 26. But as this Court recently emphasized, an interpretation of a statutory phrase

that is "plausible in the abstract" fails when it is "ultimately inconsistent with both the text and context of the statute as a whole." *Sturgeon v. Frost*, 136 S. Ct. 1061, 1070 (2016); *see FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 133 (2000) ("[T]he words of a statute must be read in their context and with a view to their place in the overall statutory scheme." (internal quotation omitted)). Indeed, Amgen's argument rests almost entirely on one word ("shall") and therefore violates the rule that words in statutes are not to be read "in isolation" but instead "'in context [since] a phrase gathers meaning from the words around it.'" *Hibbs v. Winn*, 542 U.S. 88, 101 (2004) (quoting *Gen. Dynamics Land Sys., Inc. v. Cline*, 540 U.S. 581, 596 (2004)) (alteration in *Hibbs*).

Read in its proper context, the "shall" in Section 262(*l*)(2)(A) creates only a mandatory condition precedent. It specifies an action that an applicant *must* take to proceed to the next step of the patent exchange process: *if* an applicant wishes to engage in the patent exchange process, it "shall" timely provide its application to the sponsor. 42 U.S.C. § 262(*l*)(2)(A); *see* Pet. App. 69a. But when the applicant does not satisfy that condition, the statute shifts the parties to a different patent resolution track. "*If* a subsection (k) applicant fails to provide [its] application," 42 U.S.C. § 262(*l*)(9)(C) (emphasis added), the sponsor immediately gains standing to commence a declaratory judgment action under the BPCIA's amendments to the Patent Act, which make that precise failure an act of

artificial infringement. Pet. App. 15a-17a; 35 U.S.C. § 271(e)(2)(C)(ii).

Section 262(*l*)(6) confirms that the word "shall" as used in subsection (*l*) does not denote a requirement that is mandatory in all circumstances. Subsection (*l*)(6) provides that at the end of the patent exchange process, "the reference product sponsor *shall* bring an action for patent infringement" on specified patents within 30 days. 42 U.S.C. § 262(*l*)(6) (emphasis added). If Amgen were correct that "shall" in subsection (*l*) means mandatory in all circumstances, then a sponsor that failed to file an immediate suit for artificial infringement would be "violating" subsection (*l*)(6). *See Powerex Corp. v. Reliant Energy Servs., Inc.*, 551 U.S. 224, 232 (2007) ("A standard principle of statutory construction provides that identical words and phrases within the same statute should normally be given the same meaning."). It is not rational to believe that Congress made it "unlawful" for a private party to opt not to sue another private party.

Instead, the BPCIA provides incentives for the sponsor to bring an immediate suit, paired with consequences if it does not. Thus, just as with the "shall" provision in subsection (*l*)(2), the requirement that a sponsor "shall" sue within a specified time frame is a condition precedent to other statutory benefits, namely, the availability of the full patent law remedies provided in Section 271(e). 35 U.S.C. § 271(e)(4), (6)(B). Just as in subsection (*l*)(2), the BPCIA expressly envisions that a sponsor might not sue until "*after* the

expiration of the 30-day period" and provides consequences in that event, namely, limiting a sponsor's available remedies. *Id.* § 271(e)(6)(A)(ii)(I), (B) (emphasis added). That same "if/then" structure is present throughout subsection (*l*).

b. Amgen also contends that its interpretation of the "shall" in subsection (*l*)(2) as always mandatory is "confirm[ed]" by the BPCIA's "juxtaposition" of "shall" with "may"; the statute's description of the application and manufacturing information as "required"; and its reference "to non-provision of that information as a 'failure.'" Cross-Pet. 26-27. That is incorrect.

Subsection (*l*)(2) uses "shall" and "may" to distinguish between (1) the information that "shall" be turned over as a mandatory condition precedent to participating in the patent exchange process, 42 U.S.C. § 262(*l*)(2)(A), and (2) the additional information that "may" be optionally provided to the sponsor but is not a condition precedent to proceeding to the next step of the patent exchange process, *id.* § 262(*l*)(2)(B). Similarly, the statute uses the word "required" to distinguish between the same two types of information—the information required by the condition precedent in subsection (*l*)(2)(A) as opposed to any additional information that might be optionally disclosed under subsection (*l*)(2)(B). *See id.* § 262(*l*)(1)(B)(i); *id.* § 262(*l*)(9)(A), (C).

Nor does the BPCIA's description of the non-provision of the subsection (*l*)(2)(A) information as a "fail[ure]" mean that providing that information is

mandatory in all circumstances or that not providing that information is somehow wrongful. *See id.* § 262(*l*)(9)(C). Indeed, the statute uses "fails to provide the application" and "application not provided" interchangeably. *Ibid.* ("Subsection (k) application not provided—If a subsection (k) applicant fails to provide the application * * *"). And the BPCIA elsewhere uses "fail[]" when there plainly is no duty. Subsection (*l*)(4)(B) is titled "Failure to reach agreement" and discusses what happens if the parties "fail to agree on a final and complete list" of patents to litigate. *Id.* § 262(*l*)(4)(B). Yet despite the use of "fail," there is no obligation to agree and certainly no means to compel agreement.

In short, "shall" in the context of Section 262(*l*) simply means that there is a statutorily defined consequence for "failure" to take a particular action.

c. Amgen posits that if an applicant does not initiate the patent exchange process by providing its application and manufacturing information under subsection (*l*)(2)(A), a sponsor would not know "which, if any, of its manufacturing patents would be infringed by the [a]pplicant's manufacturing processes." Cross-Pet. 28. This policy objection is baseless and provides no reason to disregard the BPCIA's text and structure. Competitors rarely have access to each other's confidential manufacturing processes before litigating. But they regularly file infringement suits based on patents they reasonably believe are infringed after diligent investigation, such as pre-suit letters seeking information about manufacturing processes.

If there is no response, the patentee can file suit without violating Federal Rule of Civil Procedure 11. *See Hoffman-La Roche Inc. v. Invamed Inc.*, 213 F.3d 1359, 1363-65 (Fed. Cir. 2000). Then, after suing, patentees use discovery to learn detailed information and amend their complaint if necessary. Pet. App. 17a.

d. Amgen contends that the Federal Circuit's ruling "upend[s]" the "regulatory balance" because the injunction authorized by 35 U.S.C. § 271(e)(4)(D) is not available when an applicant does not initiate the patent exchange process by disclosing its application. Cross-Pet. 30. Amgen contends this provision "creates a mandatory permanent injunction." *Id.* at 29. But Amgen cites no support for that characterization, which runs counter to this Court's consistent rejection of invitations to read statutory provisions as requiring the automatic issuance of injunctions without examination of "traditional equitable considerations." *eBay Inc. v. MercExchange, L.L.C.*, 547 U.S. 388, 392-93 (2006).

In any event, the Section 271(e)(4)(D) injunction is available only in narrowly defined circumstances that will rarely occur: when there is patent litigation that proceeds to a final decision in the Federal Circuit before the reference product's statutory period of exclusivity expires. *See* 35 U.S.C. § 271(e)(4)(D) (cross-referencing 42 U.S.C. § 262(k)(6) & (7)); *see* 42 U.S.C. § 262(*l*)(5)(B)(ii)(II). Amgen's period of exclusivity expired long ago, so it would not have had access to this provision even if Sandoz had provided its application. Moreover, the statute separately provides sponsors

with the ability to obtain an injunction under 35 U.S.C. § 271(e)(4)(B)—without any condition precedent related to the patent exchange process. There is thus no imbalance created by the Federal Circuit's interpretation.

e. Amgen's discussion of unenacted pre-BPCIA legislation sheds no light on the meaning of the BPCIA. *Cf.* Cross-Pet. 30-31 (citing *Chickasaw Nation v. United States*, 534 U.S. 84, 93 (2001)). Here, the Federal Circuit's interpretation of the BPCIA does not depend on "read[ing] back into the Act" a word or phrase that Congress "deleted" during consideration of the actual bill that became the BPCIA. *Chickasaw Nation*, 534 U.S. at 93. Instead, Amgen invokes bills from previous Congresses that went nowhere and that proposed different biosimilar schemes. And Amgen cites nothing from the legislative history of the BPCIA itself attributing any significance to the differences Amgen highlights. *See Mead Corp. v. Tilley*, 490 U.S. 714, 723 (1989) (observing that "mute intermediate legislative maneuvers are not reliable indicators of congressional intent") (quotation marks and citation omitted).

f. Finally, contrary to Amgen's suggestion, the fact that both the petition and the conditional cross-petition present questions related to the interpretation of the BPCIA is no reason to grant review of the cross-petition. The cross-petition must itself satisfy this Court's certiorari standards. It does not.

B. The Court Of Appeals Correctly Affirmed Dismissal Of Amgen's California UCL And Conversion Claims For State Law Reasons Independent Of Whether Withholding The Application Was "Unlawful"

In addition to concluding that Sandoz had not violated the BPCIA by withholding its application, the court of appeals affirmed the judgment dismissing Amgen's complaint on alternative state law grounds. Those bases for dismissal independently support the judgment below, yet Amgen's cross-petition does not even acknowledge them, much less demonstrate that they warrant this Court's review. They do not. *See The Wharf (Holdings) Ltd. v. United Int'l Holdings, Inc.*, 532 U.S. 588, 596 (2001) (noting that the Court does not "ordinarily" consider "state-law issue[s]"); *see generally* Eugene Gressman et al., *Supreme Court Practice* 261 (9th ed. 2007) (discussing this Court's "strong reluctance" to review questions of state law).

As noted above, the only causes of action on appeal were asserted under California law. Amgen acknowledges that it "did not assert a private right of action under the BPCIA." Amgen 15-1039 Br. in Opp. 28. Instead, Amgen contended that Sandoz's alleged failures to comply with the BPCIA were "unlawful" for purposes of the UCL and that the UCL authorized Amgen to secure an injunction. Pet. App. 9a-10a. Amgen also asserted a state law claim for conversion based on Sandoz's use of "Amgen's approved license on Neupogen by filing an [application] referencing Neupogen

but refusing to provide Amgen the benefits to which it is entitled under § 262(*l*)." Pet. App. 28a-29a.

The court of appeals affirmed dismissal of all of Amgen's state law claims—with respect to both the notice of commercial marketing (the subject of Sandoz's certiorari petition) and Sandoz's withholding of its application (the subject of Amgen's cross-petition). Pet. App. 26a, 31a. Yet with respect to Amgen's claim regarding the notice of commercial marketing provision, the court of appeals nonetheless fashioned a cause of action and nationwide injunctive remedy as a matter of federal law. Pet. App. 31a; 15-1039 Pet. 18-19, 31-35.[4] Because the Federal Circuit created a federal cause of action to enforce Amgen's interpretation of the notice of commercial marketing provision, that portion of its decision squarely presents the federal question posed by Sandoz's certiorari petition. *See* 15-1039 Pet. 31-36.

By contrast, the court of appeals created no federal remedy with respect to Amgen's claim based on Sandoz's withholding of its application. Instead, the court rejected those UCL and conversion claims not only because Sandoz's withholding of its application was lawful under the BPCIA (*supra* Part A), but also

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[4] In contrast to the nationwide injunction the court of appeals granted Amgen as a matter of federal law on the notice of commercial marketing provision, a California UCL injunction would have necessarily been limited to California. *See Allergan, Inc. v. Athena Cosmetics, Inc.*, 738 F.3d 1350, 1359-60 (Fed. Cir. 2013), *cert. denied*, 135 S. Ct. 2886 (2015).

because those claims suffered from independent state law defects.

1. California law bars a UCL remedy for Amgen because of the BPCIA's express exclusive remedies provision

California law provides that UCL remedies are not permitted when the underlying law "expressly provide[s]" that the remedies in that law are exclusive. Cal. Bus. & Prof. Code § 17205; *see Loeffler*, 324 P.3d at 76 (action under UCL can be barred where "another statutory scheme provides the exclusive means for resolving disputes"). For example, when an underlying statute provides that "its remedies 'are the exclusive remedies available,'" additional remedies under the UCL are foreclosed. *Stop Youth Addiction, Inc. v. Lucky Stores, Inc.*, 950 P.2d 1086, 1099 (Cal. 1998) (quoting Cal. Civ. Code § 7104).

Here, as noted above, the BPCIA's amendments to the Patent Act expressly provide that patent remedies "are the *only* remedies which may be granted by a court" for the failure to provide a biosimilar application. 35 U.S.C. § 271(e)(4) (emphasis added). Accordingly, even assuming that Amgen's interpretation of the BPCIA were correct and Sandoz violated it by not providing its application, the court of appeals correctly held that additional UCL remedies for that "violation" are unavailable as a matter of California law. *See* Pet. App. 27a; *see also* Pet. App. 67a n.4 (district court's characterization of Amgen's contention that it could

look for remedies beyond the BPCIA's "self-contained statutory scheme" as "untenable").

Specifically, Section 271(e)(2)(C)(ii) makes the very conduct about which Amgen complains—an applicant *both* submitting a biosimilar application *and* failing to provide the application and manufacturing information to the sponsor under subsection (*l*)(2)(A)—an act of artificial infringement under paragraph (2). 35 U.S.C. § 271(e)(2)(C)(ii). As the Federal Circuit explained, "35 U.S.C. § 271(e)(4) provides 'the *only* remedies which may be granted by a court for an act of infringement described in paragraph (2).'" Pet. App. 18a (emphasis by court of appeals). Those remedies are patent-based remedies, and the BPCIA does not include "any non-patent-based remedies for a failure to comply with paragraph (*l*)(2)(A)." Pet. App. 17a.

To try to avoid the exclusivity of the remedies in Section 271(e)(4), Amgen discusses in isolation the declaratory judgment actions referred to in subsection (*l*)(9). Amgen observes that (unlike Section 271(e)(4)), subsection (*l*)(9) includes no express "only remedies" language. Cross-Pet. 34. As an initial matter, Amgen fails entirely to address the dispositive question: whether *as a matter of California law* the statement of exclusivity in Section 271(e)(4) would bar additional UCL remedies. Pet. App. 27a. Amgen's cross-petition should be denied on that basis alone.

In any event, Amgen's effort to separate the two BPCIA sections fails. Amgen addresses the declaratory judgment provisions (Cross-Pet. 32-35) independently from the artificial infringement provisions (*id.* at 35-38), arguing that neither standing alone is "remedial" or "an exclusive remedy." But these provisions cannot be considered in isolation. Without the BPCIA's amendments to the Patent Act creating an artificial act of infringement, the sponsor would have no action under the Declaratory Judgment Act (or any other statute) based on an applicant's withholding of its application. That act of artificial infringement (with its exclusive remedies limitation) is what enables the sponsor to bring a declaratory judgment suit under subsection (*l*)(9). *See Glaxo Grp. Ltd. v. Apotex, Inc.*, 376 F.3d 1339, 1344, 1351 (Fed. Cir. 2004).

Amgen also observes that Section 262(*l*)(9)(C) does not specifically refer to a declaratory judgment action over process patents. Cross-Pet. 34. Again, Amgen errs by reading the provision in isolation. As the court of appeals noted, 35 U.S.C. § 271(e)(2)(C)(ii) expressly "allows the [sponsor] to assert process patents." Pet. App. 16a n.3.

Amgen next asserts that "[f]ailing to provide the [application] and manufacturing information is *not* an act of infringement" under Section 271(e), asserting that the court of appeals "read[] a limitation into infringement under section 271(e)(2)(C)(ii)." Cross-Pet. 37. But that limitation is in the text of the provision itself:

> It shall be an act of infringement to submit— * * * if the applicant for the application *fails to provide the application and information required under section [262](l)(2)(A)* of such Act, an application seeking approval of a biological product for a patent that could be identified pursuant to section [262](*l*)(3)(A)(i) of such Act.

35 U.S.C. § 271(e)(2)(C)(ii) (emphasis added). If there is no such failure, there is no artificial infringement under Section 271(e)(2)(C)(ii).

Amgen also contends that the artificial infringement action authorized by 35 U.S.C. § 271(e)(2)(C)(ii) is not "remedial." Cross-Pet. 35. Congress expressly disagrees. It identified that provision as a "*remed[y]*" for failure to provide an application—indeed as the "only" one. 35 U.S.C. § 271(e)(4) (emphasis added). The fact that "the remedies provided under section 271(e)(4) are remedies for * * * infringement and not for a failure to provide the information required under subparagraph 262(*l*)(2)(A)" (Cross-Pet. 37) is a feature, not a defect. The exclusive focus on patent infringement is entirely consistent with the statutory design; the statute provides no basis for imputing additional remedies as a matter of California law. As Judge Chen correctly observed: "Entitled 'Patents,' § 262(*l*) of the BPCIA concerns one thing: patent litigation." Pet. App. 45a (Chen, J., dissenting).

Finally, even if Amgen were right that the court of appeals erred in determining that the BPCIA "expressly provide[s]" that its remedies are exclusive

within the meaning of California law such that it precludes a UCL remedy, correcting that supposed error would not decide any federal question. As noted, Amgen waived the separate question of whether the BPCIA provides an implied federal right of action to enforce disclosure of the biosimilar application (although the Federal Circuit nevertheless went on to provide Amgen such a right of action with respect to the notice of commercial marketing). Under federal law, implication of such a private right of action can be foreclosed even absent an express statement of exclusive remedies like the one in 35 U.S.C. § 271(e)(4). *See Touche Ross & Co. v. Redington*, 442 U.S. 560, 571 (1979) (rejecting argument that right of action should be inferred because "Congress did not express an intent to deny a private cause of action"). Without evidence of Congress's affirmative intent to *create* the right of action in question, such an action is unavailable—whether or not Congress included a statement expressly foreclosing added remedies. *See ibid.*; *Alexander v. Sandoval*, 532 U.S. 275, 286 (2001). Accordingly, the Federal Circuit's consideration in isolation of the exclusive remedies provision in Section 271(e)(4) for purposes of determining whether it precluded a UCL remedy provides a poor vehicle for consideration of any question of federal law.

2. *Amgen does not challenge the court of appeals' affirmance of the dismissal of its California conversion claim, which is correct in any event*

The court of appeals likewise affirmed dismissal of Amgen's California conversion claim on two alternative grounds: (1) Amgen failed to establish that Sandoz's withholding of its application was a "wrongful act" and (2) given the BPCIA's authorization of an applicant's use of "'publicly-available information' regarding the reference product in its application" and the expiration of Amgen's twelve-year exclusivity period, Amgen "fail[ed] to show that it has an *exclusive* right to possession of its approved license on Neupogen to sustain its claim of conversion under California law." Pet. App. 29a.

Amgen's cross-petition does not appear to challenge the court of appeals' affirmance of dismissal of its conversion claim at all, much less specifically allege error with respect to the alternative holding on Amgen's lack of an "exclusive right" under California law. Even if Amgen had attempted to challenge this aspect of the judgment, it would have provided no basis for review. The court of appeals' decision is correct, and, in any event, this Court need not grant certiorari to address the elements of a California claim for conversion.

Moreover, there are additional alternative state law grounds to affirm dismissal of Amgen's conversion claim. *See* Sandoz CA Br. 57-58. In particular, Amgen

has not properly pleaded conversion of an intangible property right under California law. The "work that Amgen did to obtain [its] license" (Amgen CA Br. 60) is not a property "interest capable of precise definition." *Alderson v. United States*, 686 F.3d 791, 796 (9th Cir. 2012). Further, California courts have consistently rejected theories that seek to expand conversion law where, as here, the proposed expansion would (1) interfere with the balance struck by a statute, such as the BPCIA, between the interests of the putative owner of intangible property rights and the interests of the public in the availability of important products and technologies; or (2) create an end-run around the requirements of patent law. *See Moore v. Regents of Univ. of Cal.*, 793 P.2d 479, 487-97 (Cal. 1990).

3. Sandoz's counterclaims provide no basis for review of Amgen's abstract BPCIA arguments

Amgen may contend on reply that the declaratory judgment entered in favor of Sandoz on Sandoz's counterclaims seeking an interpretation of the BPCIA (Pet. App. 31a, 83a; CA JA A22) presents federal questions that provide a vehicle for this Court's review. That would be incorrect; that judgment cannot be separated from Amgen's flawed state law claims.

As Sandoz explained when it first asserted its declaratory judgment counterclaims, they were relevant to the "disagreement between Amgen and Sandoz" only because "[i]nterpretation of the BPCIA would resolve

Amgen's claims for conversion and violation of California's Unfair Competition law." CA JA A281 (Sandoz Counterclaims ¶ 29). Indeed, Amgen in its answer to the counterclaims stated that they failed to state a claim "because they are merely defenses directed at an element of [Amgen's] claims, and are not proper counterclaims." Dist. Ct. Dkt. No. 28, Plaintiffs' Answer to Defendant Sandoz Inc.'s Counterclaims and Affirmative Defenses at 9 (Second Affirmative Defense).

The lower courts' disposition of Sandoz's counterclaims cannot be reviewed in isolation because they do not rest on any federal cause of action. *See Harris Cty. v. MERSCORP Inc.*, 791 F.3d 545, 552 (5th Cir. 2015) ("[T]he Declaratory Judgment Act alone does not create a federal cause of action."). A declaratory judgment action may be pursued only when "'a coercive action' brought by 'the declaratory judgment defendant,'" here Amgen, "'would necessarily present a federal question.'" *Medtronic, Inc. v. Mirowski Family Ventures, LLC*, 134 S. Ct. 843, 848 (2014) (quoting *Franchise Tax Bd. of Cal. v. Constr. Laborers Vacation Trust for S. Cal.*, 463 U.S. 1, 19 (1983)). If the declaratory judgment defendant would have no cause of action to bring such a coercive action—as Amgen would not here because of its waiver of any federal cause of action and the state law defects in the causes of action it did pursue—a declaratory judgment action may not proceed on its own. Accordingly, if the Court does not review and overturn the Federal Circuit's conclusions that Amgen's affirmative claims fail as a matter of California law, the Court's review of the lower courts'

disposition of Sandoz's counterclaims would yield only an advisory opinion on an abstract question of statutory interpretation.

CONCLUSION

The conditional cross-petition for a writ of certiorari should be denied.

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IN THE

Supreme Court of the United States

AMGEN INC. AND AMGEN MANUFACTURING LIMITED,

Cross-Petitioners,

v.

SANDOZ INC.,

Cross-Respondent.

ON CROSS-PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

REPLY BRIEF FOR THE CONDITIONAL CROSS-PETITIONERS

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CORPORATE DISCLOSURE STATEMENT

Pursuant to Rule 29.6 of the Rules of this Court, Respondents Amgen Inc. and Amgen Manufacturing Limited state the following:

Amgen Inc. is a publicly held corporation. Amgen Inc. has no parent corporation and no publicly held corporation owns 10% or more of its stock.

Amgen Manufacturing Limited is a wholly owned subsidiary of Amgen Inc. Apart from Amgen Inc., there is no publicly held corporation with a 10% or greater ownership in Amgen Manufacturing Limited.

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ARGUMENT

Amgen's cross-petition is conditional. Because the provisions of the BPCIA on which Sandoz and Amgen each petition for review use identical language in an integrated statutory scheme, the interpretation of one bears on the interpretation of the other. The Court should review them together, if at all.

Sandoz recasts Amgen's question presented, to argue that this Court would have to reach questions of state law to avoid an advisory opinion. The Federal Circuit's resolution of Amgen's state-law claims, however, turned on federal law, not state law. It held that those claims failed in relevant part because they rested on Amgen's construction of subparagraph 262(*l*)(2)(A) of the BPCIA, which the Federal Circuit rejected. (*See* Pet. App. at 26a-29a.) The Federal Circuit also decided Sandoz's counterclaims for declaratory judgments regarding the rights and remedies available under the BPCIA where an Applicant refuses to provide the subparagraph 262(*l*)(2)(A) disclosure. The Federal Circuit directed the district court "to enter judgment on those counterclaims consistent with [the Federal Circuit's] opinion" and its "interpretation of the BPCIA." (*See id.* at 3a-4a, 31a.)

There is a ripe, federal-law controversy between Sandoz and Amgen about the meaning of subparagraph 262(*l*)(2)(A), which this Court can resolve without venturing into state-law issues.

I. SANDOZ OFFERS NO REASON WHY THIS COURT SHOULD REVIEW ONLY ONE COMPONENT OF AN INTEGRATED STATUTE, RATHER THAN BOTH

Sandoz argues that Amgen's conditional cross-petition does not meet the Court's certiorari standards, and that the question presented is not sufficiently important to warrant review. (Sandoz Opp'n ("Opp'n") at 4; *see also id.* at 23.) To be sure, Supreme Court Rule 12.5 requires that a cross-petition "comply in all respects with this Rule and Rule 14." Amgen met that requirement and Sandoz makes no effort to demonstrate otherwise.

The question, then, is not compliance with the rules, but whether this Court should accept both petitions if it accepts either. The issues raised by Sandoz's and Amgen's petitions are inextricably intertwined. (*See* Cross-Pet. at 8, 22-25.) Both 42 U.S.C. § 262(*l*)(2)(A) and § 262(*l*)(8)(A) are triggered by the Applicant's choice to seek FDA licensure under the subsection (k) pathway, rather than the traditional approval pathway. Both state that the Applicant "shall provide" specific things, yet differently composed majorities of the Federal Circuit panel construed one "shall" as mandatory and one as optional. (*See* Pet. App. at 12a-18a, 23a-26a.) Thus, Amgen's cross-petition is no less important than the petition on which it is contingent.

Sandoz's arguments confirm that the Court should treat the two petitions in tandem. Sandoz asserts that the Federal Circuit erred by treating

subparagraph 262(*l*)(8)(A) as a "standalone" provision, "disconnecting the notice provision from the BPCIA's patent resolution regime." (Pet. at 22.) And in opposing Amgen's cross-petition, Sandoz argues that the word "shall" in subparagraph 262(*l*)(2)(A) must be understood in the context of subsection 262(*l*) as a whole. (Opp'n at 21.)

The parties agree that the provisions of subsection 262(*l*) are an integrated series of steps. Thus, if the Court determines that the construction of subparagraph 262(*l*)(8)(A) is ripe for review and that this case is the proper vehicle to grant Sandoz's petition, the Court should also grant Amgen's cross-petition on the proper construction of subparagraph 262(*l*)(2)(A), so that these related provisions of an integrated statute can be construed in the context of subsection 262(*l*) as a whole.

II. SANDOZ OFFERS NO TENABLE DEFENSE OF THE FEDERAL CIRCUIT'S TREATMENT OF "SHALL" AS OPTIONAL

Sandoz's ten-page argument that "the BPCIA does not require a biosimilar applicant to disclose its application to the sponsor in all circumstances," (Opp'n at 1, 2-3, 14-23), cannot change the simple and clear statutory command. When an Applicant submits an application for FDA approval under the abbreviated pathway of subsection 262(k), as Sandoz did, it "shall provide . . . the information required to be produced [its aBLA and manufacturing information] pursuant to" paragraph 262(*l*)(2). 42 U.S.C. § 262(*l*)(1)(B)(i). And, paragraph 262(*l*)(2) in turn expressly states that

"[n]ot later than 20 days after" FDA notifies the Applicant that its aBLA "has been accepted for review," the Applicant "shall provide to the reference product sponsor a copy of the application submitted to the Secretary under subsection (k), and such other information that describes the process or processes used to manufacture the biological product that is the subject of such application," and that the Applicant "may provide to the reference product sponsor additional information requested by or on behalf of the reference product sponsor." 42 U.S.C. § 262(*l*)(2)(A), (B). In holding that the Applicant is not required to provide the subparagraph 262(*l*)(2)(A) information, the Federal Circuit erred.

This Court's precedents are clear that the verb "shall" is generally mandatory, and that where "shall" is used in juxtaposition to the verb "may"—as it is here—the "shall" is clearly mandatory. (*See* Cross-Pet. at 26 (citing *Nat'l Ass'n of Home Builders v. Defenders of Wildlife*, 551 U.S. 644, 661-62 (2007); *Jama v. Immigration & Customs Enf't*, 543 U.S. 335, 346 (2005); *Lopez v. Davis*, 531 U.S. 230, 241 (2001); *Anderson v. Yungkau*, 329 U.S. 482, 485 (1947); *United States ex rel. Siegel v. Thoman*, 156 U.S. 353, 359-60 (1895)).)

Sandoz now argues that the distinction between "shall" and "may" in paragraph 262(*l*)(2) is not that one is mandatory and the other optional, but that one is a "condition precedent to proceeding to the next step of the patent exchange process" and the other is not. (Opp'n at 20.)

While it is true that several of the steps after subparagraph 262(*l*)(2)(A) depend on the Applicant providing its aBLA and manufacturing information, that does not make provision of that information optional. The only conditions precedent to providing that information, as the statute states expressly, is an Applicant's submission of its aBLA under subsection (k) and notification by FDA that the application has been accepted for review. 42 U.S.C. § 262(*l*)(1)(B)(i), (*l*)(2)(A). Congress did not say that an Applicant that wishes to initiate the patent-exchange procedures "shall" provide its aBLA and manufacturing information, while an Applicant that chooses, or opts, or elects not to initiate the process may decline to provide that information. On the contrary, Congress gave Applicants the choice of electing the new abbreviated pathway of subsection (k) and the attendant obligations that arise under subparagraph 262(*l*)(2)(A), or filing their FDA applications through the traditional 262(a) pathway without triggering such obligations. Indeed, Sandoz's opening assertion that the BPCIA does not require disclosure "in all circumstances" is curious (Opp'n at 1), because Sandoz never identifies <u>any circumstance</u> in which it contends that disclosure is required.

The surrounding statutory context further confirms that the "shall" in subparagraph 262(*l*)(2)(A) mandatory. In at least four places, the BPCIA refers to provision of the aBLA and manufacturing information as "required," and twice refers to non-provision of that information as a "fail[ure]." *See* 42 U.S.C. § 262(*l*)(1)(B)(i), (*l*)(9)(A),

(*l*)(9)(C); 35 U.S.C. § 271(e)(2)(C)(ii). Sandoz acknowledges, as it must, that the statute consistently uses "required" when referring to actions that "shall" be performed under 262(*l*)(2)(A), but not to those that "may" be performed pursuant to 262(*l*)(2)(B). (*See* Opp'n at 20.)

Sandoz also has no valid response to the consequences of its own argument. As Amgen showed in its cross-petition, there is a mandatory injunction under the BPCIA where a Sponsor prevails on a patent in a paragraph 262(*l*)(6) lawsuit while the Sponsor is within the data-exclusivity period of paragraph 262(k)(6). (*See* Cross-Pet. at 29-30 (citing 35 U.S.C. § 271(e)(4)(D)).) If an Applicant can choose not to provide its aBLA and manufacturing information, it can prevent the Sponsor from bringing a paragraph 262(*l*)(6) lawsuit and thus deprive the Sponsor of this remedy. Sandoz argues that a paragraph 262(*l*)(6) lawsuit during the 262(k)(6) exclusivity period "will rarely occur," and further argues that the injunction in 35 U.S.C. § 271(e)(4)(D) cannot be mandatory despite its plain text. (Opp'n at 22.) The Federal Circuit found the opposite, that "aBLAs will often be filed during the 12-year exclusivity period." (Pet. at 22a.) That Sandoz's statutory interpretation would render an express injunctive remedy a dead letter confirms that Sandoz is wrong.

The statutory purpose also confirms that subparagraph 262(*l*)(2)(A) is mandatory. (*See* Cross-Pet. at 27-31.) The BPCIA requires manufacturing patents to be included in the patent-dispute procedures, *see* 42 U.S.C. § 262(*l*)(3), yet

without the Applicant's aBLA and manufacturing information the Sponsor would likely have no way of knowing which, if any, of its manufacturing patents would be infringed by the Applicant's (nearly always secret) manufacturing processes. (*See* Cross-Pet. at 28.) Sandoz's only answer to this is to suggest that "Competitors rarely have access to each other's confidential manufacturing processes before litigating" yet file infringement suits. (Opp'n at 21.) But that, too, ignores the statutory text. Congress explicitly made patents that cover the "making" of the biological product part of the patent lists and information provisions of paragraph 262(*l*)(3). That is why Congress required the Applicant to provide not only its aBLA but also "such other information that describes the process or processes used to manufacture the biological product." 42 U.S.C. § 262(*l*)(2). That this requirement is unusual, or even unique, in patent law is a reason to enforce the statute, not to render it optional.

Finally, Sandoz argues that where the Applicant refuses to provide the subparagraph 262(*l*)(2)(A) disclosures, the Sponsor's exclusive remedies are a declaratory judgment action under subparagraph 262(*l*)(9)(C) or a patent-infringement suit under 35 U.S.C. 271(e)(2)(C)(ii). As explained in Amgen's cross-petition, neither of these provisions is remedial, much less an exclusive remedy. (*See* Cross Pet. at 32-38.) Sandoz's argument depends on 35 U.S.C. § 271(e)(4), which provides the exclusive remedies "[f]or an act of infringement described in paragraph (2)." (emphasis added). But failing to provide the aBLA and manufacturing information is

not an act of infringement, and in suggesting otherwise the Federal Circuit erred. Before the BPCIA was enacted, Congress had made it "an act of infringement to submit" to the FDA an application under the Federal Food, Drug, and Cosmetic Act (most prominently, an Abbreviated New Drug Application). *See* 35 U.S.C. § 271(e)(2)(A), (B). The BPCIA extended this "act of infringement" to applications submitted under the Public Health Service Act seeking approval of a biological product. Thus, each of 35 U.S.C. § 271(e)(2)(C)(i) and (ii) states that "[i]t shall be an act of infringement to submit . . ., an application." The words that precede the comma determine which patents are infringed; the act of infringement is submitting an application. In a patent-infringement action on that technical act of infringement, section 271(e)(4) limits the available remedies for that infringement, as it does in the Hatch-Waxman Act context. That does not mean, however, that the remedies in section 271(e)(4) are the only remedies for a violation of the BPCIA.

Sandoz muddies the waters by arguing that the technical act of infringement in 35 U.S.C. § 271(e)(2)(C)(ii) is necessary to allow a declaratory judgment action. (Opp'n at 28.) Sandoz misapprehends the law. The technical act of infringement in section 271(e)(2) is not necessary to create declaratory-judgment jurisdiction. Rather, "section 271(e)(2) makes it possible for the district court to exercise its section 1338(a) jurisdiction." *Allergan, Inc. v. Alcon Labs., Inc.*, 324 F.3d 1322, 1330 (Fed. Cir. 2003) (citing *Glaxo, Inc. v.*

Novopharm, Ltd., 110 F.3d 1562, 1569 (Fed. Cir. 1997)). The dictum in the case Sandoz cites, *Glaxo Group. Ltd. v. Apotex, Inc.*, 376 F.3d 1339 (Fed. Cir. 2004), does not change this settled law. Subparagraph 262(*l*)(9)(C) lifts the limitation imposed on the Sponsor by subparagraph 262(*l*)(9)(A) and 28 U.S.C. § 2201(b): bringing "any" declaratory judgment action on specified patents. This limitation is not specific to declaratory judgment actions based on section 271(e), nor does it exclude actions based on anticipated future infringement under section 271(a), (b), (c), (g) or (f).

In holding that section 271(e)(4) sets forth the exclusive remedies for an Applicant's failure to provide its aBLA and manufacturing information, the Federal Circuit erred. If this Court is inclined to review the portion of the Federal Circuit's decision challenged by Sandoz's petition, it should grant Amgen's cross-petition and review this aspect of the decision as well.

III. SANDOZ WRONGLY ASSERTS THAT THE FEDERAL CIRCUIT'S DECISION RESTED ON INDEPENDENT STATE-LAW GROUNDS

Sandoz argues that reversal of the Federal Circuit's construction of the BPCIA would be an "advisory opinion" unless this Court were also to reach questions of state law. (Opp'n at 1.) Sandoz asserts that the Federal Circuit rejected Amgen's Cal. Bus. & Prof. Code § 17200 claim and conversion claim on both federal and state-law grounds. (*Id.* at 1, 2, 3, 25-26.)

That is not what happened. The Federal Circuit affirmed the dismissal of Amgen's state law claims "based on [its] interpretation of the BPCIA," including subparagraph 262(*l*)(2)(A). (Pet. App. at 26a.) That is, because the Federal Circuit held that subparagraph 262(*l*)(2)(A) does not require an Applicant to provide its aBLA and manufacturing information, Sandoz did not violate that provision, and the court affirmed the dismissal of Amgen's state-law claims, both of which depended on a violation of federal law. (*See id.* at 27a-30a.)

In addition, the court's interpretation of subparagraph 262(*l*)(2)(A) as optional rested on its conclusion that subparagraph 262(*l*)(9)(C) is remedial because it creates consequences for non-compliance with subparagraph 262(*l*)(2)(A). (*See id.* at 16a-17a.) The court further relied on the patent-infringement provision and remedies of 35 U.S.C. § 271(e)(2)(C)(ii) and (e)(4). (*See id.* at 18a.) It concluded that Amgen could not state a Section 17200 claim precisely because the court held that federal law—35 U.S.C. § 271(e)(4) and 42 U.S.C. § 262(*l*)(9)(C)—provides an exclusive remedy for Sandoz's failure to provide its aBLA and manufacturing information under subparagraph 262(*l*)(2)(A). (*See id.* at 27a.) While Sandoz relies on the Federal Circuit's statement that California law bars a Section 17200 remedy where the underlying statute itself provides a remedy (Opp'n at 26-30; Pet. App. at 27a), there was no independent state-law ruling there; the Federal Circuit's decision about California law turned entirely on its construction of the BPCIA.

Likewise, with respect to Amgen's conversion claim, Sandoz seeks to find a state-law ground of decision in the Federal Circuit's holding that Amgen did not have "an *exclusive* right to possession of its approved license on Neupogen to sustain its claim of conversion under California law." (Pet App. at 29a; Opp'n at 12.) But that, too, was a holding about federal law. The Federal Circuit relied on the BPCIA provisions permitting an Applicant to reference the Sponsor's license and a Sponsor's period of data exclusivity. (*See* Pet App. at 29a (citing 42 U.S.C. § 262(k)(2), (k)(7)(A)).)

Finally, Sandoz argues that "there are additional alternative state law grounds to affirm dismissal of Amgen's conversion claim," citing its brief in the Federal Circuit for arguments about intangible property rights under California law. (Opp'n at 31.) The Federal Circuit did not reach any of those arguments, and Amgen does not seek their review here. If there are unique state-law issues following from a construction of the BPCIA by this Court that require resolution on remand, they can be addressed by the Federal Circuit or district court.

All that Amgen's cross-petition asks this Court to review is the Federal Circuit's holding that subparagraph 262(*l*)(2)(A) is optional even though it provides that the Applicant "shall" provide "required" information. That is a holding about a federal statute, in violation of this Court's precedent. It is not a state-law issue at all.

IV. SANDOZ'S ARGUMENTS ABOUT PRIVATE RIGHTS OF ACTION AND ITS OWN COUNTERCLAIMS ARE NO BASIS TO GRANT ONLY SANDOZ'S PETITION

Sandoz makes two final arguments opposing Amgen's cross-petition.

First, Sandoz argues that even if Amgen were right about subparagraph 262(*l*)(2)(A), Amgen waived the separate question of whether the BPCIA provides a implied federal right of action. (*See* Opp'n at 29-30.)

This is a defense to an argument Amgen never made. Amgen's cross-petition does not, and need not, depend on its assertion of a private right of action. There is no private-right-of-action issue here. (*See* Amgen Opp'n to Sandoz's Pet. at 28-29.)

Second, Sandoz argues that its counterclaims provide no basis to review Amgen's supposedly "abstract" BPCIA arguments. (Opp'n at 32-34.) That is incorrect. Sandoz's counterclaims sought a declaration of the rights of the parties where an Applicant refuses to provide the information under subparagraph 262(*l*)(2)(A). (*See* Pet. App. at 64a.) That was not an "abstract" dispute; Sandoz refused to provide that information to Amgen. The Federal Circuit interpreted the BPCIA to permit non-disclosure of that information (*id.* at 18a), and directed the district court to enter judgment on Sandoz's counterclaims consistent with that statutory interpretation. (*Id.* at 4a, 31a.) Sandoz's

counterclaims thus squarely present the question in Amgen's cross-petition.

To that end, if this Court were to grant Amgen's cross-petition, reverse the Federal Circuit, and hold that subparagraph 262(*l*)(2)(A) is mandatory, the Federal Circuit and the district court could address any further questions of remedy on remand. There are unlikely to be any such issues, as Sandoz's argument has always been that the BPCIA permits Applicants to decline to provide that information. If this Court holds that Sandoz is wrong, it is hard to imagine Sandoz (or any other Applicant) flouting this Court's holding.

If the Court is not inclined to take both Sandoz's petition and Amgen's conditional cross-petition, the best course is to deny both. There are other BPCIA cases percolating in the district courts and before the Federal Circuit. They may well be better vehicles than this case. But if this Court is inclined to grant Sandoz's petition, it should grant Amgen's cross-petition too. None of Sandoz's arguments provides any basis to review only half of the Federal Circuit's decision.

CONCLUSION

This Court should deny Sandoz's Petition in No. 15-1039 for the reasons set forth in Amgen's brief in opposition. But if this Court grants Sandoz's Petition, it should also grant Amgen's Conditional Cross-Petition.

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AMGEN INC. AND AMGEN MANUFACTURING LIMITED,
Cross-Petitioners,

v.

SANDOZ INC.,
Cross-Respondent.

ON WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

REPLY BRIEF FOR AMGEN INC. AND AMGEN MANUFACTURING LIMITED

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CORPORATE DISCLOSURE STATEMENT

The corporate disclosure statement included in Amgen's opening brief remains accurate.

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Sandoz continues to treat the BPCIA's mandatory, integrated procedures for the resolution of patent disputes like an à la carte menu from which it can pick and choose. But Congress did not craft an exceedingly detailed framework, providing that the sponsor and applicant "shall" fulfill each step, so that applicants could ignore it at will. Had Congress meant to make the framework optional, as it did in some earlier bills, it would have said so.

Sandoz's argument in response to the cross-petition is that, when Congress specified that a biosimilar applicant "shall" provide its application and manufacturing information to the reference product sponsor, 42 U.S.C. §262(*l*)(2)(A), it meant only that the applicant "shall" do so *if* it "wishes to engage in the information exchange" prescribed by §262(*l*). Sandoz Br. 35. That is a surpassingly strange interpretation of the word "shall." As the statute specifies, the applicant's real choice comes when it decides whether to follow §262(a)'s regular pathway to approval or take advantage of §262(k)'s streamlined pathway, which allows it to save hundreds of millions of dollars and years in development by relying on the sponsor's safety and efficacy data. If an applicant avails itself of the streamlined pathway, it must proceed with the process Congress mandated. 42 U.S.C. §262(*l*)(1)(B)(i) ("When a subsection (k) applicant submits an application under subsection (k), such applicant *shall provide* ... the information required to be produced pursuant to paragraph (2)[.]" (emphasis added)).

Sandoz insists that Congress turned "shall" into "may" when it preserved the sponsor's patent rights even if the applicant fails to comply with §262(*l*)(2)(A). 35 U.S.C. §271(e)(2)(C)(ii); 42 U.S.C. §262(*l*)(9)(C). That argument vastly overreads the provisions in question,

which serve merely to avoid incoherent cross-references to other statutory provisions—not to create an entirely separate dispute-resolution pathway. Section 271(e)(2)(C)(ii) recognizes that the set of patents implicated in an artificial-infringement action (patents listed under §262(*l*)(3)) could otherwise contain no patents if the applicant breached §262(*l*)(2)(A), because the exchange of patent lists would not be triggered. It therefore allows suit on patents that *could* be listed if the applicant complied with §262(*l*)(2)(A). Section 262(*l*)(9)(C) makes a similar adjustment to preserve the limits that §262(*l*)(9)(A) and (B) would have placed on the applicant had it complied with §262(*l*)(2)(A), while clarifying that the sponsor retains its preexisting right to bring a declaratory-judgment action under 28 U.S.C. §2201. Neither provision remedies the harm caused to the sponsor by the applicant's breach, as they both leave the sponsor unable to identify in a timely and reliable manner which of its patents would be infringed. Neither, therefore, provides any basis to conclude that Congress intended to offer applicants that have chosen to file under the §262(k) pathway a *further* choice whether or not to comply with the disclosure requirement.

Indeed, it is nonsensical to suggest that, whenever Congress specifies some consequences of a statutory violation, it transforms the violation into a permissible choice. For example, if a statute states that a manufacturer "shall" not emit certain pollutants and may be fined if it does, no one would deny that a polluter (even one that pays the fine) is breaking the law. When Sandoz chose to take advantage of the §262(k) pathway while ignoring Congress's command that it "shall" provide Amgen with its application and manufacturing information, it similarly broke federal law, and conse-

quently is engaging in an "unlawful ... business act or practice" in violation of California's Unfair Competition Law, Cal. Bus. & Prof. Code §17200.

Although the Court need not decide whether federal law authorizes orders enforcing §262(*l*)(2)(A), because Amgen sought such relief under state law, courts plainly may issue such orders in the course of adjudicating an infringement or declaratory-judgment action properly brought by the sponsor. Sandoz admits the sponsor can obtain the application and manufacturing information through discovery in such an action. It makes no sense, then, for Sandoz to suggest (at 21-22) that an order compelling the applicant to provide the required information is "entirely different" from adjudicating the underlying infringement claim.

Sandoz's interpretation would make a hash of the orderly path to resolution of patent disputes that Congress created. If the parties follow the steps set forth in §262(*l*), they can resolve their disputes in an efficient, sensible way. The applicant's early disclosure of its application and manufacturing information permits the sponsor to determine the set of patents implicated by the biosimilar—something that can vary widely even across biosimilars of the same reference product. The subsequent exchanges enable the parties to narrow their disputes, and streamline any necessary litigation, through early disclosure of the parties' contentions.

In place of that orderly process, Sandoz offers only complications and uncertainty. Under Sandoz's view, a sponsor may never even learn that an application has been filed. And if the sponsor does learn as much, it may lack sufficient information about the applicant's proposed product, uses, and manufacturing processes to know which patents may be infringed, and sufficient

information about the identity of the applicant and its affiliates to know whom and where to sue. Sandoz would have the sponsor bring suit on its best guess, include any conceivably relevant patent, and request the application and manufacturing information in discovery. Whether or not that would work, it would constitute an astonishing waste of resources for courts and litigants when compared with the alternative of simply requiring the applicant to obey §262(*l*)(2)(A).

If the Court holds that parties must take the steps Congress provided they "shall" take, the statute will work as Congress intended. If the statute's mandates are instead treated as a menu of options, Congress's carefully crafted system will be continually challenged and evaded, spawning extensive litigation. This Court should not discard Congress's coherent and comprehensive scheme in favor of Sandoz's stumbling-in-the-dark, anything-goes approach.

I. APPLICANTS MUST PROVIDE SPONSORS WITH THEIR APPLICATIONS AND MANUFACTURING INFORMATION

A. The Text Requires Disclosure

1. The statutory text specifies that the applicant "*shall* provide" its application and manufacturing information to the sponsor "[n]ot later than 20 days" after the FDA accepts the application for review. 42 U.S.C. §262(*l*)(2)(A) (emphasis added). The word "shall" indicates a mandatory command. Amgen Br. 58-60. That should be the end of the matter.

Sandoz argues (at 34-35) that the applicant's disclosure obligation becomes "mandatory" only if the applicant chooses to participate in the information-exchange process. That interpretation improperly writes into the statute a new prefatory clause: "*[I]f an applicant*

wishes to engage in the information exchange, it 'shall' timely provide its application." Sandoz Br. 35 (some emphasis added). Congress included no such clause in the statute.

Any conceivable ambiguity is erased by §262(*l*)(1)(B)(i), the first place in §262(*l*) where the disclosure requirement is mentioned. As that provision makes clear, the applicant's §262(*l*)(2)(A) obligation is triggered by its choice to pursue FDA approval under §262(k)'s streamlined pathway instead of §262(a)'s standard pathway:

> *When a subsection (k) applicant submits an application under subsection (k)*, such applicant *shall provide* to the persons described in clause (ii), subject to the terms of this paragraph, confidential access to *the information required to be produced pursuant to paragraph (2)* and any other information that the subsection (k) applicant determines, in its sole discretion, to be appropriate[.]

(Emphases added.) Having chosen to submit a §262(k) application, an applicant has no further choice about whether to comply with §262(*l*)'s information-exchange process.

Other provisions reinforce that construction. Amgen Br. 58-59. For example, Congress's repeated references to the applicant's "fail[ure]" to provide the "required" §262(*l*)(2)(A) information underscore the mandatory nature of the obligation. 35 U.S.C. §271(e)(2)(C)(ii); 42 U.S.C. §262(*l*)(9)(A), (C). Sandoz responds (at 37) by noting §262(*l*)(4)(B)'s reference to the parties' "fail[ure] to agree" on a list of patents for phase-one litigation. But that provision at most establishes that Congress's use of "fail" did not *create* an ob-

ligation to reach agreement where the statute requires only "good faith negotiations." 42 U.S.C. §262(*l*)(4)(A). The obligation to obey §262(*l*)(2)(A) is created not by the word "fail" but by the phrase "shall provide." The statute's references to the applicant's "fail[ure]" to do what is "required" by §262(*l*)(2)(A) simply confirm that Congress used "shall" in its ordinary, mandatory sense.

2. Sandoz points to several supposedly optional uses of "shall," to suggest that Congress meant "shall" in an optional sense here as well. None of Sandoz's arguments is persuasive.

Sandoz first invokes (at 35) a provision stating that the sponsor "shall bring an action for patent infringement" within 30 days of the parties' exchange of their patent lists. 42 U.S.C. §262(*l*)(6). Separate provisions specify that if a sponsor fails to bring the §262(*l*)(6) action within 30 days with respect to a listed patent, the "sole and exclusive remedy" that a court can grant for infringement is a reasonable royalty, in effect foreclosing injunctive relief or lost profits on that patent. 35 U.S.C. §271(e)(6)(A)(ii)(I), (B). Sandoz assumes from those provisions that a sponsor that fails to file a timely action cannot be said to "'violate'" any mandatory obligation. Sandoz Br. 35. But Sandoz offers no basis for that incorrect conclusion. If the applicant has fulfilled its obligations up to that point, the statute provides that a sponsor *must* file a §262(*l*)(6) action within the specified time.[1]

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[1] It is unlikely that the applicant would seek an order enforcing §262(*l*)(6). If a sponsor fails to comply with §262(*l*)(6), it primarily burdens its *own* rights by limiting its remedy for infringement. Applicants are unlikely to complain about that narrowing of the sponsor's potential remedies, especially since applicants retain

Sandoz also invokes (at 37-38) statutes and rules stating that an appeal "shall" be taken by a particular date. For example, 28 U.S.C. §2101(a) states that "[a] direct appeal to the Supreme Court ... shall be taken within thirty days after the entry of the interlocutory or final order, judgment or decree." But that statute (and similar provisions) use the passive voice to indicate that *any* appeal shall be taken within the specified period—not that the losing party in the lower court *must* take an appeal. The statute would have an entirely different meaning if it affirmatively required, much as §262(*l*)(2)(A) does, that the losing party "shall appeal" the judgment "within thirty days." *See also infra* pp. 13-14 (party may waive only provision meant for its benefit, not opponent's benefit).

In short, nothing in the text supports Sandoz's argument that applicants that avail themselves of §262(k) thereafter may choose whether to comply with §262(*l*)(2)(A) or any of the other requirements set forth in the BPCIA's detailed dispute-resolution scheme. Where Congress wanted to give the applicant discretion, it said so. *E.g.*, 42 U.S.C. §262(*l*)(1)(B)(i) (con-

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the right to obtain patent certainty by filing a declaratory-judgment action on phase-one patents. By contrast, an applicant's violation of §262(*l*)(2)(A) primarily burdens the *sponsor*. *See infra* pp. 13-14 (discussing principle that one party cannot waive a statutory provision intended for the benefit of another party).

Sandoz's argument (at 35) regarding constitutional concerns with enforcing §262(*l*)(6) strays even further into the realm of the theoretical. Even had Sandoz substantiated the argument, it would provide no reason to hold that the provisions actually before this Court are not mandatory or cannot be enforced. Notably, Sandoz does not claim that enforcing the provisions at issue here would raise any constitutional concerns.

trasting the materials that "shall" be provided under §262(*l*)(2)(A) with "any other information that the subsection (k) applicant determines, in its sole discretion, to be appropriate"); *id.* §262(*l*)(2)(B) (applicant "may provide ... additional information requested by" the sponsor); *id.* §262(*l*)(1)(A) (parties may agree to alternative confidentiality rules). In contrast, Congress repeatedly and exclusively spoke in mandatory terms when it established the requirement at issue here.

B. The BPCIA's History And Purpose Make Clear That §262(*l*)(2)(A) Requires Disclosure

As Amgen's opening brief explains (at 60-64), Congress enacted §262(*l*) to ensure sponsors would have a meaningful opportunity to protect their patent rights before a biosimilar's launch. Sandoz's interpretation of §262(*l*)(2)(A) cannot be reconciled with that objective.

Were Sandoz right that an applicant could unilaterally deny the sponsor the information Congress directed it to provide, the sponsor could not meaningfully assess its patents, engage in informed pre-suit licensing discussions or other attempts to avoid litigation, or obtain a mandatory injunction against infringement through a suit under §262(*l*)(6). The sponsor's only way to protect its patent rights would be to file an infringement action—likely on information and belief, and likely including dozens or hundreds of conceivably relevant patents—without actually knowing which of its patents the biosimilar would infringe. That is not what Congress intended in creating a *streamlined* dispute-resolution process.[2]

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[2] As Amgen's opening brief explains (at 67-72), Sandoz's position on §262(*l*)(8)(A) exacerbates these concerns by creating the

1. Sandoz relies heavily (at 38) on 35 U.S.C. §271(e)(2)(C), which makes the submission of a biosimilar application an act of infringement whether or not the applicant complies with §262(*l*)(2)(A). Sandoz seems to assume (at 38) that a sponsor would *prefer* the applicant to violate §262(*l*)(2)(A) because it then "gains far more control over the scope and timing of any infringement suit" and "can sue immediately on all its patents." That is utterly wrong.

As an initial matter, if the applicant refuses to comply with §262(*l*)(2)(A), the sponsor may not even learn that an application has been filed (let alone that the FDA has accepted it for review). Any right to sue for infringement is meaningless if the applicant's infringement remains hidden or its detection obscured or delayed by the applicant's violation of §262(*l*)(2)(A). Sandoz downplays this concern, arguing that sponsors can scour "public information about biosimilar development." Sandoz Br. 3; *see id.* at 17. But as Amgen's opening brief explains (at 69-70), securities disclosures, clinical trial databases, and the like are insufficient to ensure access to the information that Congress explicitly provided sponsors should have. Sandoz offers no response.

If a sponsor learns that an application has been filed, despite a §262(*l*)(2)(A) violation, Sandoz expects the sponsor to "sue immediately on *all* its patents." Sandoz Br. 38 (emphasis added). No sponsor would prefer such a blind, burdensome proceeding to the informed, well-ordered proceedings prescribed by §262(*l*). Biologics are enormously complex molecules

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possibility that a sponsor will be unaware of the biosimilar before launch.

manufactured in living organisms. Amgen Br. 6-11. A biologic's structure and composition depends on its manufacturing process. *Id.* And the manufacturing process can include complex steps: developing cell lines, expanding and culturing the cells, removing any impurities, deactivating viruses, and so forth.[3] A sponsor's portfolio might include dozens or hundreds of patents that relate to these steps and thus *could* be implicated by the applicant's process. *E.g.*, CAJA472 (explaining classes of patents owned by Amgen that related, *e.g.*, to "purification of protein"). If the sponsor does not sue on all such patents, it may risk losing the opportunity to assert them at all, as Amgen's experience in the *Hospira* case makes evident. Amgen Br. 61-62.[4] It may likewise have to sue on every potentially relevant product and method-of-use patent, without knowing anything about the specific structure or formulation of the biosimilar or the uses for which the applicant seeks approval, simply to learn whether there is a factual basis to assert the patents. It is absurd to think a spon-

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[3] Conner et al., *The Biomanufacturing of Biotechnology Products, in Biotechnology Entrepreneurship* 351, 355 (Shimasaki ed., 2014).

[4] Sandoz's response to *Hospira* (at 41 n.7) misses the point. Amgen sought discovery on patents that were absent from the §262(*l*)(3) lists only because Hospira declined to provide its manufacturing information as required by §262(*l*)(2)(A), leaving Amgen unable to determine which manufacturing-process patents could reasonably be asserted. Appellant's Br. 10, Dkt. 28, No. 2016-2179 (Fed. Cir. Sept. 12, 2016). If the Federal Circuit affirms the denial of discovery, Amgen and other sponsors will have no choice in future cases but to blindly file suit on every potentially relevant patent, even though most will ultimately prove irrelevant because the applicant is not using the particular processes claimed in the patents.

sor—not to mention Congress or the courts—would prefer this inefficient outcome to §262(*l*)'s procedures, which guarantee the sponsor access to the applicant's product and process information at the outset of the dispute-resolution process and allow the parties to narrow the dispute to what is actually relevant.[5]

2. Sandoz also suggests (at 40) that, in enacting §271(e)(2)(C)(ii), Congress must have thought a sponsor would have enough information even without the §262(*l*)(2)(A) disclosures to determine which patents were infringed. That is incorrect. Congress was well aware of the complexity of biologics, the inevitable differences between the reference product and the biosimilar, and the importance of the specific manufacturing process used for each product. 155 Cong. Rec. E7683 (2009) (a biologic "is unique to the cell lines and specific process used to produce it" (statement of Rep. Eshoo)); *see also* Amgen Br. 9. None of the relevant product or process details is available from public sources. That is why Congress intended the sponsor to use the §262(*l*)(2)(A) information to "determin[e] ... whether a claim of patent infringement could reasonably be asserted if the subsection (k) applicant engaged in the manufacture, use, offering for sale, sale, or importation" of the biosimilar. 42 U.S.C. §262(*l*)(1)(D).

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[5] Equally meritless is Sandoz's suggestion (at 38-39) that a sponsor would prefer to "force the applicant to launch its product" without patent certainty. Amgen has explained the price erosion and other irreparable harm sponsors face when a competitor's infringing product floods the market. *E.g.*, Amgen Br. 41; C.A. Dkt. 55 at 16-19; *see also* Professors' Br. 17-19. No sponsor would willingly risk such irreparable harm.

Sandoz's argument misunderstands the reason Congress enacted §271(e)(2)(C)(ii). The provision is simply a fail-safe to ensure that the applicant cannot entirely stall the dispute-resolution process by refusing to provide the required disclosures. It does not make the violation of §262(*l*)(2)(A) an act of infringement. Rather, the *submission* of a §262(k) application is the artificial act of infringement. The patents deemed infringed include any listed under §262(*l*)(3)(A) if the applicant complies with §262(*l*)(2)(A). 35 U.S.C. §271(e)(2)(C)(i). And if the applicant does not comply, the patents deemed infringed by the applicant's submission include any that the sponsor *could* list under §262(*l*)(3)(A). *Id.* §271(e)(2)(C)(ii). This fail-safe provision is not a distinct, alternative dispute-resolution pathway; it is simply an adjustment to the §262(*l*) pathway to avoid the anomaly that would occur if there were no §262(*l*)(3)(A) list by virtue of the applicant's failure to provide the §262(*l*)(2)(A) information. That Congress contemplated that a sponsor might be forced to sue without the §262(*l*)(2)(A) information in no way indicates that Congress considered such an outcome remotely desirable or an acceptable "choice" that the applicant can make in lieu of following §262(*l*)(2)(A)'s mandate. Section 271(e)(2)(C)(ii) expressly and simply establishes that the submission of a biosimilar application is an act of infringement whether or not the applicant complies with §262(*l*)(2)(A)'s mandate—nothing more.

3. Sandoz's view would also allow infringing applicants unilaterally to limit a sponsor's remedies for infringement. Where a sponsor within the 12-year data exclusivity period prevails on "an action for infringement ... under section [262](*l*)(6)," 35 U.S.C. §271(e)(4)(D) provides that "the court *shall order* a

permanent injunction prohibiting any infringement of the patent" until it expires. (Emphasis added.) If the applicant could choose not to follow the steps set forth in §262(*l*), thus precluding a §262(*l*)(6) action, it would improperly cut off the sponsor's access to a mandatory permanent injunction.

Sandoz's responses are meritless. It first suggests (at 42) that treating the injunction as mandatory is inconsistent with *eBay Inc.* v. *MercExchange, LLC*, 547 U.S. 388 (2006). But *eBay* requires a court to apply the traditional four-factor test when exercising its *equitable discretion* whether to grant injunctive relief, *id.* at 391-392; it does not apply to statutorily mandated injunctions like the one prescribed by §271(e)(4)(D). That distinction also answers Sandoz's next argument: Although a *discretionary* injunction remains available under §271(e)(4)(B), Sandoz would deny the sponsor the certainty of mandatory injunctive relief. And although Sandoz notes (at 43) that Amgen was ineligible for a mandatory injunction, because a sponsor can obtain that remedy only if the biologic's 12-year exclusivity period has not yet passed, that is irrelevant. The availability or unavailability of the injunction in this particular case is no reason to adopt Sandoz's erroneous interpretation as the standard governing all future cases.

As Judge Newman recognized below, Pet. App. 41a, Sandoz's position would allow an applicant to decide for itself whether to comply with provisions—like §262(*l*)(2)(A) and §262(*l*)(8)(A)—that are meant primarily for the *sponsor*'s benefit. A party can waive compliance with a statutory or contractual provision if the provision is "intended for *his* benefit." *Shutte* v. *Thompson*, 82 U.S. (15 Wall.) 151, 159 (1873) (emphasis added); *see also United States* v. *Mezzanatto*, 513 U.S. 196, 200-201 (1995). A party can, for example, waive its

right to appeal an adverse judgment because doing so works only to its detriment. *Cf.* Sandoz Br. 37-38; *supra* p. 7. But a party "cannot waive or disregard a provision that benefits those in an adverse position." Pet. App. 41a (Newman, J., concurring in part and dissenting in part). That is what Sandoz seeks to do. Section 262(*l*)(2)(A) protects the *sponsor*'s rights to assert all relevant patents and obtain a mandatory injunction if warranted. Applicants cannot unilaterally treat compliance with §262(*l*)(2)(A) as optional simply because they regard the possibility of an immediate, blunderbuss infringement action as more "expedien[t]," Sandoz Br. 42.

4. Finally, Sandoz nowhere disputes that its proposed interpretation would reinstate precisely the approach Congress rejected year after year during the biosimilars debates: a scheme giving the applicant discretion whether to participate in any patent-dispute resolution process prior to launch. *See* Amgen Br. 63-64; BIO Br. 21-22 & n.7; Professors' Br. 32-36. Sandoz makes the unremarkable point (at 43) that congressional inaction can be unpersuasive evidence of congressional intent. But this Court has previously looked to closely related bills considered and rejected by Congress to inform the meaning of the statute ultimately enacted. *See, e.g.*, *Arizona* v. *United States*, 132 S. Ct. 2492, 2504 (2012); *Hamdan* v. *Rumsfeld*, 548 U.S. 557, 579-580 (2006); *Trbovich* v. *United Mine Workers of Am.*, 404 U.S. 528, 532-535 (1972). Here, some Members of Congress and stakeholders advocated for an optional dispute-resolution scheme, but Congress imposed a mandatory one instead. Sandoz seeks to rewrite the BPCIA to replace the position that prevailed with the one that lost.

II. COURTS MAY ORDER APPLICANTS TO COMPLY WITH THE DISCLOSURE REQUIREMENT

Sandoz errs in asserting that courts lack the power to order compliance with §262(*l*)(2)(A).

A. Amgen Sought An Injunction Under State Law

As Amgen's opening brief explains (at 64), this Court need not decide whether federal law authorizes orders to enforce §262(*l*)(2)(A) because Amgen sought such relief under California's Unfair Competition Law (UCL). Sandoz recognized as much in opposing certiorari. Opp. 2.

Sandoz accuses Amgen (at 44) of "fail[ing] to note" the supposed holding below that a UCL "injunction is unavailable on state law grounds." But the Federal Circuit did not say a UCL injunction is unavailable to enforce a mandatory duty created by §262(*l*)(2)(A). It held a UCL injunction was unavailable only on the theory that §262(*l*)(2)(A) does *not* create a mandatory duty. Pet. App. 27a. Amgen's cross-petition (at 25-39) and opening brief (at 58-64) dispute that erroneous holding and the Federal Circuit's reliance on it to dispose of the UCL claim.

The Court should also reject Sandoz's argument (at 44 n.9) that "any attempt to use California law to 'enforce' the [BPCIA] would be preempted and would in any event support an injunction only in California." Sandoz previously disavowed any preemption argument (*e.g.*, CAJA1854), and the Federal Circuit accordingly did not consider it. Pet. App. 26a n.5. This Court "ordinarily do[es] not consider claims that were neither raised nor addressed below," *Travelers Cas. & Sur. Co. of Am.* v. *Pacific Gas & Elec. Co.*, 549 U.S. 443, 455

(2007), much less ones expressly disavowed. In any event, Sandoz's newly minted and poorly developed argument lacks merit. *See* Amgen Br. 43; AbbVie Br. 19-25; U.S. Br. 12-16, *Bank of Am., N.A.* v. *Rose*, No. 13-662 (U.S. May 27, 2014), 2014 WL 2202864.

Moreover, the propriety of a nationwide injunction is not at issue here. Unlike in *Allergan, Inc.* v. *Athena Cosmetics, Inc.*, 738 F.3d 1350, 1358-1360 (Fed. Cir. 2013), which involved an injunction against the sale of a product anywhere in the United States, the act Amgen sought to require—Sandoz's provision of its application and manufacturing information—is a one-time occurrence, not a nationwide course of conduct. There is no doubt that the district court could lawfully have ordered Sandoz, a party subject to its jurisdiction, to perform that required act.[6]

B. Federal Law Authorizes Orders To Enforce The Disclosure Requirement

If the Court reaches the question whether federal law authorizes orders to enforce §262(*l*)(2)(A), it should answer that question in the affirmative.

1. As Amgen's opening brief explains (at 43-46, 64), it is irrelevant whether the BPCIA confers a private right of action to enforce §262(*l*)(2)(A). Cases on

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[6] Even if an order requiring compliance with §262(*l*)'s mandates could be construed as a nationwide injunction, it would be permissible because—unlike the injunction in *Allergan*—it would not "impose[] the UCL on entirely extraterritorial conduct regardless of whether the conduct in other states causes harm to California," 738 F.3d at 1358. The consequences of an applicant's breach of §262(*l*) cannot be limited to states outside California, and here, Sandoz's breach directly harmed Amgen, a California company.

private rights of action address when private litigants, rather than the government, may sue to enforce a statute or regulation that does not expressly afford them a cause of action. Here, the government plays no enforcement role, and no one doubts that sponsors have a right to sue applicants. The only question is whether, in a suit properly before it, the court may order the applicant to comply with its procedural obligations under the BPCIA. That question is answered by the presumption that federal courts possess equitable power to remedy violations of the law in cases properly before them. *Amgen Inc.* v. *Apotex Inc.*, 827 F.3d 1052, 1064 (Fed. Cir. 2016); Amgen Br. 45-46.

Sandoz mistakenly assumes (at 20-23, 44) that orders requiring compliance with §262(*l*) are unrelated to the infringement or declaratory-judgment actions that a sponsor may bring.[7] Sandoz is right that a court adjudicating a patent-infringement suit obviously could not, for example, order the defendant to comply with its pollution-control obligations. But orders requiring compliance with §262(*l*)'s procedural requirements are intimately related to infringement and declaratory-judgment actions, because they permit the efficient litigation and adjudication of such actions.

Consider Sandoz's account (at 40-41) of how a sponsor should proceed if, due to the applicant's failure to provide its application and manufacturing information, the sponsor lacks sufficient knowledge to determine which of its patents may be infringed. Sandoz would

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[7] Sandoz's arguments about the enforceability of §262(*l*)(2)(A) (at 44) incorporate by reference its arguments about the enforceability of §262(*l*)(8)(A) (at 20-28). Amgen likewise addresses the latter in the course of responding to the former.

have the sponsor blindly sue for a declaratory judgment of infringement, then obtain the application and manufacturing information through "normal discovery tools." But if the sponsor can obtain the same materials in discovery, then it makes no sense for Sandoz to suggest that an up-front order requiring the applicant to comply with its statutory duty, avoiding the unnecessary rigmarole and delay of discovery, would somehow be unrelated to the underlying suit. Requiring the applicant to comply with §262(*l*)(2)(A) is not "entirely different" from adjudicating the underlying infringement claim, as Sandoz argues (at 21-22); it is part and parcel of the same enterprise.

Such orders fall well within the district courts' inherent authority "to manage their own affairs so as to achieve the orderly and expeditious disposition of cases," *Link* v. *Wabash R.R. Co.*, 370 U.S. 626, 630-631 (1962); *see also, e.g.*, *Chambers* v. *NASCO, Inc.*, 501 U.S. 32, 43-44 (1991); *Landis* v. *North Am. Co.*, 299 U.S. 248, 254 (1936). "There is universal acceptance in the federal courts that, in carrying out" its duty to "effectuat[e] the speedy and orderly administration of justice ... , a district court has the authority to enter pretrial case management and discovery orders designed to ensure that the relevant issues to be tried are identified, that the parties have an opportunity to engage in appropriate discovery and that the parties are adequately and timely prepared so that the trial can proceed efficiently and intelligibly." *United States* v. *W.R. Grace*, 526 F.3d 499, 508-509 (9th Cir. 2008) (en banc). An order requiring the applicant to produce the information required by §262(*l*)(2)(A), to facilitate the efficient reso-

lution of patent-infringement claims, is a paradigmatic exercise of this authority.[8]

2. Even were the relevant question whether §262(*l*)(2)(A) supports a private right of action, the answer would be that it does.

The private-right-of-action analysis boils down to a simple question: Did Congress intend to enable private parties to enforce a statutory or regulatory requirement? Amgen Br. 50. Here, there is no federal enforcement of §262(*l*)(2)(A). As a result, the real question becomes whether Congress intended it to be enforceable at all. The answer is yes: Congress regarded §262(*l*)(2)(A) as a mandate, not a choice, *see supra* pp. 4-14, and a mandate that cannot be enforced is no mandate at all. It follows that Congress meant for §262(*l*)(2)(A) to be enforceable by private litigants.

Sandoz attacks (at 24) the notion "that when Congress regulates conduct between private parties, courts can invent causes of action and remedies." Amgen makes no such argument. The only fair inference from §262(*l*)'s text, structure, and purpose is that Congress *did* intend §262(*l*)(2)(A) to be enforceable by sponsors.

3. Finally, Sandoz renews its argument (at 33-34, 44) that courts cannot order compliance with §262(*l*)(2)(A) because other provisions—35 U.S.C. §271(e)(2)(C)(ii) and 42 U.S.C. §262(*l*)(9)(C)—allegedly state the exclusive consequences of non-compliance. As Amgen's opening brief explains (at 65-67), neither of those provisions remedies the harm caused by an applicant's breach of §262(*l*)(2)(A), and they should not be

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[8] If additional authority were needed, it is supplied both by 35 U.S.C. §283 and by the All Writs Act, 28 U.S.C. §1651.

read to foreclose an order to comply with §262(*l*)(2)(A), which actually *would* remedy the harm.

Section 262(*l*)(9)(C) preserves the limits that §262(*l*)(9)(A) and (B) would have imposed on the applicant's ability to bring a declaratory-judgment action had it complied with §262(*l*)(2)(A). It also adjusts for the fact that §262(*l*)(9)(A)'s restrictions on both the applicant and the sponsor presuppose the existence of patent lists under §262(*l*)(3) and (4) or (5)(B), and therefore would be incoherent where such lists have not been created. *See* 42 U.S.C. §262(*l*)(9)(A) (applies to "any patent that is described in clauses (i) and (ii) of paragraph (8)(B)"); *id.* §262(*l*)(8)(B)(i)-(ii) (describing patents with reference to the §262(*l*)(3) and (4) or (5)(B) lists). At the same time, §262(*l*)(9)(C) clarifies that the sponsor retains its preexisting right to seek declaratory relief under 28 U.S.C. §2201 in appropriate cases—reinforcing that, by its plain terms, the restriction §262(*l*)(9)(A) places on a sponsor's right to bring a declaratory-judgment action is inapplicable when the applicant does not make the §262(*l*)(2)(A) disclosure. That preservation of the sponsor's background rights, combined with adjustments to avoid obsolete cross-references to patent lists the applicant has prevented from being created, was never intended to be an exclusive remedy for the applicant's breach.

Indeed, one must suspend disbelief to conclude that Congress intended §262(*l*)(9)(C) to remedy the harm caused by a §262(*l*)(2)(A) violation. Even on Sandoz's account, it could do so only through a convoluted chain of events. If the sponsor manages to learn that an application has been submitted, which is not guaranteed, then §262(*l*)(9)(C) confirms the sponsor can (1) file a declaratory-judgment action on *potentially* relevant patents, even though it lacks the information that would

allow it to determine which of its patents will be infringed and who the proper defendant would be; and (2) seek the application and manufacturing information in discovery, with all the attendant costs and complications, and with the risk that the district court may erroneously deny discovery (as occurred in the *Hospira* case, *see* Amgen Br. 61; *supra* p. 10 n.4). Even if this process eventually allows the sponsor to obtain the information to which it is entitled, that is likely to happen only after weeks or months of pointless delay. Here, for example, the statute entitled Amgen to receive Sandoz's application and manufacturing information by July 27, 2014, but Amgen did not obtain the application through discovery until February 9, 2015—108 days after filing suit and just 25 days before the FDA licensed Sandoz's biosimilar. Pet. App. 8a, 63a. This would be a bizarre way for Congress to have envisioned the enforcement of §262(*l*)(2)'s straightforward command that the applicant "shall provide" its application and manufacturing information within "20 days."

Sandoz is equally wrong to suggest that 35 U.S.C. §271(e)(2)(C)(ii) creates the exclusive remedy for a violation of §262(*l*)(2)(A). As explained above (at 12), a §262(*l*)(2)(A) violation is not an act of infringement. The *submission* of a §262(k) application is the act of infringement under either §271(e)(2)(C)(i), where the applicant complies with §262(*l*)(2)(A), or §271(e)(2)(C)(ii), where it does not. Section 271(e)(2)(C)(ii) simply alters the language of §271(e)(2)(C)(i), from "is identified" to "could be identified," to reflect the reality that there may be no patent list without §262(*l*)(2)(A) compliance. Section 271(e)(2)(C)(ii) can no more be regarded as an exclusive remedy for a violation of §262(*l*)(2)(A) than §262(*l*)(9)(C) can.

Moreover, statutes and rules often specify retrospective consequences of an unlawful act without foreclosing orders meant to prevent the unlawful act from occurring in the first place. No one would think, for example, that a court cannot issue an order forbidding the spoliation of electronically stored information in civil discovery simply because a procedural rule specifies certain consequences for spoliation. Nor would anyone think that a court could not order the parties to expedite an action under the Hatch-Waxman Act, simply because the statute also authorizes the court to extend the 30-month stay of market entry if the parties violate the mandate to "reasonably cooperate in expediting the action," 21 U.S.C. §355(j)(5)(B)(iii). Likewise here: Congress's decision to set forth certain retrospective effects of a §262(*l*)(2)(A) violation, none of which actually remedies the harm caused by the violation, does not preclude an order to comply with the requirement.

Finally, Sandoz's invocation of 35 U.S.C. §271(e)(4) (at 45) is a non sequitur. That provision circumscribes the "remedies which may be granted by a court for an act of infringement described in" §271(e)(2). But as Amgen's opening brief explains (at 66-67), a breach of §262(*l*)(2)(A) is not "an act of infringement."

* * *

The question presented may arise from a complicated statute, but the answer is ultimately straightforward: When Congress provides that a person "shall" do something, it is generally imposing a command, not offering a choice. That mandatory construction is reinforced where an opt-out construction would create absurd results. And it is doubly reinforced where complying with the mandate would be straightforward. The Court should reject Sandoz's contrary approach, which

would eviscerate the statutory scheme for no reason other than Sandoz's desire not to be bound by it.

CONCLUSION

The Federal Circuit's judgment on §262(*l*)(2)(A) should be reversed.

Respectfully submitted.

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Cross-Respondent.

ON WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

BRIEF FOR *AMICI CURIAE* 11 PROFESSORS IN SUPPORT OF AMGEN, INC., *ET AL.* AS CROSS-PETITIONERS

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Access to Life-Saving Medicine Act, H.R. 6257, 109th Cong. (2006) 33, 34

Affordable Biologics for Consumers Act, S. 1505, 110th Cong. (2007) 32-33

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Biologics Price Competition and Innovation Act of 2007, S. 1695, 110th Cong. (2007) 33

Follow-On Biologics: Hearing on Examining Food and Drug Administration Follow-On Biologics, Generally Referred to As a Biotechnology Derived Protein Drug (Or Biologic) That is Comparable to a Novel, Previously Approved Biologic and That is Approved With less Supporting Data Than the Innovator Biologic Before the Comm. On Health, Ed., Labor, and Pensions, 110 Cong. 36 (2007) 30

Letter from Frank Pallone, Jr., Chairman, & Nathan Deal, Ranking Member, Subcomm. on Health, Comm. on Energy & Commerce, U.S. House of Reps., to 35 groups (Apr. 3, 2008) 29

Letter from Paulo Costa, CEO, Novartis Corp., to Frank Pallone, Jr. and Nathan Deal, H. Subcomm. On Health, 29 (May 1, 2008) 30

Letter from Robert Pelzer, CEO Novartis, to the Federal Trade Commission (Sept. 29, 2008), *available at* https://www.ftc.gov/sites/default/files/documents/public_comments/emerging-health-care-competition-and-consumer-issues-537778-00009/537778-00009.pdf 31

Patient Protection and Innovative Biologic Medicines Act of 2007, H.R. 1956, 110th Cong. (2007) 32, 33

INTEREST OF *AMICI CURIAE*[1]

The *amici curiae* comprise eleven professors who teach and write on patent law and policy, and the economics of the biopharmaceutical industry, and who are thus concerned with the integrity of the legal system that secures innovation to its creators and to the companies that commercialize it in the marketplace. Although the members of the *amici* may differ amongst themselves on other aspects of modern patent law and policy, they are united in their professional opinion that this court should reverse and remand the Court of Appeals for the Federal Circuit's decision in this case at least because the appellate court's contorted interpretation of the Biologics Price Competition and Innovation Act (BPCIA) threatens to undermine the statutory mechanism for timely and cost–efficient resolution of patent disputes between biologic drug innovators and manufacturers of biosimilar drugs. The names and affiliations of the members of the *amici* are set forth in Appendix A.

SUMMARY OF ARGUMENT

The United States has led the world for decades in the development of important new medicines for serious and life–threatening diseases. This innovation is made possible by robust patent protection. The pathway to approval of a new biologic drug is lengthy, costly, and

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1. Pursuant to Supreme Court Rule 37.6, *amici curiae* state that no counsel for any party authored this brief in whole or in part, and that no person or entity other than *amici curiae* or their counsel made a monetary contribution to the preparation or submission of this brief. Counsel of Record for both Cross–Petitioners and Cross–Respondent consented in writing to the filing of this brief.

risky. Once a biologic drug has been introduced to the market, however, a competitor can develop a biosimilar at a fraction of the innovator's time and cost. Meaningful patent protection ensures that the innovator can recover its investment in the biopharmaceutical research and development that made the new medicine possible. Because it is impossible to recover market power after launch of an infringing product (even if that product is removed from the market), only a scheme that permits patent enforcement prior to biosimilar market launch will provide adequate protection of innovator patents. The Federal Circuit's interpretation of the patent information exchange provisions of the BPCIA will undermine the essential role of patents in stimulating investment in this important research. If biosimilar applicants may elect not to participate in the premarket patent information exchange, biologic drug innovators will be frustrated in their efforts to assert their patent rights.

Immediately after enactment of the BPCIA, one author of this brief published extensive research demonstrating that the process culminating in its enactment afforded biosimilar manufacturers many opportunities over many years to address the scope, contours, and design of the patent information exchange and litigation provisions. Cross–Respondent Sandoz was offered, and seized upon, many opportunities to state its contrarian case during the legislative process. After years of deliberation and careful consideration of stakeholder comments, Congress disagreed with Sandoz, enacting a biosimilar pathway that, from its outset, required mutual information exchange between parties. Indeed, Sandoz immediately denounced the enacted legislation because the information exchange was mandatory. Thus Sandoz is attempting to

litigate an issue that was expressly and unambiguously settled by Congress. The proper remedy for Sandoz is a legislative amendment, not a judicial reworking of a settled policy matter. For these reasons, *amici* submit that this Court should reverse and remand the decision of the Federal Circuit.

ARGUMENT

I. MEANINGFUL PATENT PROTECTION FOR BIOLOGIC DRUGS IS ESSENTIAL TO ENSURE THAT THE UNITED STATES RETAINS ITS PLACE AT THE FOREFRONT OF INNOVATION IN MEDICINE

A. For decades the United States has led the world in developing important new medicines for serious and life–threatening diseases

Innovation in medicine over the last century is responsible for profound improvements in public health, both domestically and globally. Vaccines led to the eradication of smallpox worldwide and virtual elimination of polio. More than 20 medicines are now available to treat HIV, though it was almost universally a death sentence less than a generation ago. Today many cancers can be effectively cured, including *for example* testicular cancer, childhood leukemia, and non–Hodgkin's lymphoma. The biotechnology revolution of the 1970s and 1980s fundamentally transformed treatment of many serious and life–threatening diseases and conditions, including type 1 diabetes, Crohn's disease, rheumatoid arthritis, and multiple sclerosis. The social value of the increased life expectancy achieved from 1970 to 1998 — much of it attributable to medical advances like these — has been

measured at around $73 trillion dollars, roughly $2.6 trillion per year.[2]

The United States has been the world leader in the scientific and medical innovation that has produced these breakthroughs. Most of the world's top biopharmaceutical companies are based in the United States.[3] U.S. companies are "testing more potential medicines in clinical trials than all other companies from the rest of the world combined."[4] Indeed, the U.S. biopharmaceutical industry accounted for over 5,000 of the approximately 7,000 medicines in development globally in 2015.[5] U.S. companies are also the primary source of biotechnology-derived products, "originating more than half of all worldwide biopharmaceutical introductions from 1982 to 2003."[6] The

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2. Kevin M. Murphy & Robert H. Topel, *Diminishing Returns?: The Costs and Benefits of Improving Health*, 46 PERSP. BIOL. & MED. S108, S118 (2003). The U.S. GDP over the same period averaged $5.8 trillion per year. *Id.*

3. William Looney, *Pharm Exec's Top 50 Companies 2016*, 36(PHARMACEUTICAL EXECUTIVE (2016), *available at* http://www.pharmexec.com/2016-pharm-exec-50 (showing that 8 of the top 15 ranked companies by prescription drug sales in 2015 are headquartered in the United States).

4. Robert D. Atkinson, *The U.S. Has Been the World's Medicine Cabinet for Too Long*, FORBES (Feb. 23, 2016, 8:30 AM), https://www.forbes.com/sites/realspin/2016/02/23/the-u-s-has-been-the-worlds-medicine-cabinet-for-too-long/#5e0c1a903719.

5. Kristina M. Lybecker, *Intellectual Property Protection for Biologics: Why the Trans-Pacific Partnership (TPP) Trade Agreement Fails to Deliver*, 22 J. COMMERC. BIOTECH. 42, 42 (2016).

6. Henry Grabowski, *Follow-On Biologics: Data Exclusivity and the Balance Between Innovation and Competition*, 7 NATURE REV. DRUG DISCOVERY 479, 483 (2008).

U.S. also accounts for more than 40 percent of the world's patents in biotechnology.[7]

Innovation by the U.S. biopharmaceutical industry not only profoundly transforms public health, it also stimulates the U.S. economy. Biopharmaceutical exports have been steadily growing, reaching $ 47 billion in 2015, nearly triple the amount in 2003.[8] The biopharmaceutical industry itself employs around 854,000 workers in the United States.[9] A broader group of bioscience companies – which includes not only biopharmaceutical research and development firms, but also the research, testing, and medical laboratories and the bioscience finance and insurance firms that flourish with a vibrant innovating industry – employed more than 1.6 million workers in 2012, representing an increase of 7.4% in a ten–year span.[10] Moreover, each position at a biopharmaceutical research company supports more than four additional jobs across the economy (ranging from construction to childcare

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7. Organisation for Economic Cooperation and Development (OECD), COMPENDIUM OF PATENT STATISTICS 18–19 (2008), *available at* www.oecd.org/dataoecd/5/19/37569377.pdf (stating that "[i]n 2005, the United States contributed to 40.6% of all biotechnology patents" and included 7 of the top 10 regions, globally, in biotechnology patenting).

8. PhRMA, 2016 BIOPHARMACEUTICAL RESEARCH INDUSTRY PROFILE 34 (2016), *available at* http://phrma-docs.phrma.org/sites/default/files/pdf/biopharmaceutical-industry-profile.pdf.

9. *Id.* at 33.

10. BIOTECHNOLOGY INDUSTRY ORGANIZATION (BIO), BIOSCIENCE ECONOMIC DEVELOPMENT IN THE STATES: LEGISLATION AND JOB CREATION BEST PRACTICES 6 (2015), *available at* https://www.bio.org/sites/default/files/files/Bioscience%20Economic%20Development%20Report_Final_6-5-15.pdf.

providers), which means that the industry supports more than 4.4 million U.S. jobs.[11]

We have profound public health, social welfare, and economic reasons to ensure that the United States remains a world leader in biopharmaceutical research and development. The questions now before this Court provide an opportunity to ensure continued investment in this sector of the economy and, through this investment, continued biopharmaceutical innovation.

B. The pathway to approval for a new biologic drug is lengthy, costly, and risky

Developing a new biologic drug today takes ten to twelve years on average, costs more than $2.5 billion, and is successful less than ten percent of the time.

To begin with, constructing and validating a commercial-scale biologic drug manufacturing facility can be time-consuming and expensive. Simply building a facility capable of the sophisticated manufacturing process required for biologic drugs can cost an estimated $200 million to $400 million and can take four years.[12] Unlike conventional small molecule drugs regulated under new drug applications, biologic drugs are generally manufactured in living systems.[13] The cells that make the active ingredient of biologic drugs are typically grown

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11. PhRMA, 2016 BIOPHARMACEUTICAL RESEARCH INDUSTRY PROFILE, *supra* note 8 at 33.

12. JOHN R. THOMAS, CONG. RESEARCH SERV., R41483, FOLLOW-ON BIOLOGICS: THE LAW AND INTELLECTUAL PROPERTY ISSUES 15 (2014).

13. 42 U.S.C. § 262(i) (2012) (defining biological products).

in massive stainless steel bioreactor vessels.[14] Feeding the cells and extracting the therapeutic protein typically requires many challenging cell culture and purification steps.[15] The production environment must be tightly controlled, from the water used to wash the tanks to the air circulating in the facility.[16] Development and validation of the manufacturing process for a new biological medicine is also, separately, time consuming and expensive.[17] The active ingredients of biologic drugs are large, complex, and hard to characterize in the laboratory.[18] Their mechanisms

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14. *See generally* FDA, BIOTECHNOLOGY INSPECTION GUIDE (Nov. 1991), https://www.fda.gov/ICECI/Inspections/InspectionGuides/ucm074181.htm (last updated Nov. 25, 2014) [hereinafter Biotechnology Inspection Guide]; MANUFACTURING PROCESS OF BIOLOGICS, INTERNATIONAL CONFERENCE ON HARMONISATION OF TECHNICAL REQUIREMENTS FOR REGISTRATION OF PHARMACEUTICALS FOR HUMAN USE 6 (2011) [hereinafter MANUFACTURING PROCESS OF BIOLOGICS], *available at* http://www.ema.europa.eu/docs/en_GB/document_library/Presentation/2011/06/WC500107832.pdfInternational Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (2011).

15. *See* Biotechnology Inspection GuideInternational Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (2011, *supra* note 14; MANUFACTURING PROCESS OF BIOLOGICS, *supra* note 14.

16. *See* Biotechnology Inspection GuideInternational Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (2011, *supra* note 14; MANUFACTURING PROCESS OF BIOLOGICS, *supra* note 14.

17. Thomas, *supra* note 12, at 15.

18. *See generally* Janet Woodcock *et al.*, *The FDA's Assessment of Follow-On Protein Products: A Historical Perspective*, 6 NATURE REV. DRUG DISCOVERY 437 (2007).

of action, and the relationship between their structural attributes and clinical functions, may not be well understood.[19] Biologic drug substances — the bulk drugs that are processed into final formulations and delivered to healthcare providers — are often heterogeneous. This can make it hard to establish and validate a manufacturing process that will consistently develop a quality product.[20]

Biologic drug development is also risky, expensive, and time–consuming because biologic drugs present a risk of immunogenicity that ordinary chemically synthesized drugs do not generally present. A biologic drug is a large protein foreign to the patient to whom it is administered, which presents a serious risk of triggering an immune response in the body.[21] The immunogenicity of a biologic drug can render that medicine ineffective or dangerous, and the consequences can be life–threatening.[22] Slight changes to the raw materials or manufacturing processes used to make a biologic drug can have profound clinical consequences.[23] For example, in the 1990s Johnson & Johnson replaced a single inactive ingredient in the vial

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19. *Id.*

20. *See generally* FDA, GUIDANCE FOR INDUSTRY, PROCESS VALIDATION: GENERAL PRINCIPLES AND PRACTICES (2011), *available at* https://www.fda.gov/downloads/drugs/guidances/ucm070336.pdf.

21. FDA, GUIDANCE FOR INDUSTRY, IMMUNOGENICITY ASSESSMENT FOR THERAPEUTIC PROTEIN PRODUCTS 2 (2014), *available at* https://www.fda.gov/downloads/drugs/guidances/ucm338856.pdf.

22. *Id.* at 3-6.

23. Kristina M. Lybecker, *When Patents Aren't Enough: Why Biologics Necessitate Data Exclusivity Protection*, 40 WM. MITCHELL L. REV. 1427, 1433 (2014).

presentation of its medicine, Eprex® (epoetin alfa) with an inactive ingredient used in the prefilled syringes of the same medicine. It began to receive more reports of pure red cell aplasia, a serious condition in which the body stops making red blood cells, from patients taking the medicine for treatment of anemia associated with chronic renal failure. The company ultimately attributed these life-threatening immunogenic reactions to the combination of the inactive ingredient substitution and the particular rubber stopper used in the vials.[24] The sensitivity of biologic drugs to slight changes in the manufacturing process complicates premarket research and development. Manufacturing processes typically evolve over the course of a clinical development program. These changes can affect the product's safety and effectiveness, and with biologic drugs it is often impossible to predict the effect the change will have on the product. Every adjustment over the course of the development program must be considered carefully, usually requiring extensive testing.[25]

Preclinical and clinical testing of biologic drugs is also time consuming and expensive. The FDA requires proof of safety and effectiveness, which must be gathered in a gradual process that begins with laboratory and animal

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24. Katia Boven *et al.*, *Epoetin-Associated Pure Red Cell Aplasia in Patients with Chronic Kidney Disease: Solving The Mystery*, 20 NEPHROL. DIAL. TRANSPLANT iii33, iii34 (2005).

25. FDA, GUIDANCE FOR INDUSTRY, DEMONSTRATION OF COMPARABILITY OF HUMAN BIOLOGICAL PRODUCTS, INCLUDING THERAPEUTIC BIOTECHNOLOGY-DERIVED PRODUCTS (1996) [hereinafter COMPARABILITY OF HUMAN BIOLOGICAL PRODUCTS], https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm122879.htm (last updated July 6, 2005).

testing and proceeds to clinical trials only if the preclinical work indicates it is safe to test in humans.[26] Several phases of human trials typically culminate in large randomized controlled clinical trials designed to test safety and effectiveness in patients.[27] For biopharmaceuticals that entered clinical trials between 1990 and 2003, the average length of the total process was 149.7 months (12.5 years), and the average length of clinical testing plus FDA approval was 97.7 months (8.1 years).[28] More recent research examining biopharmaceuticals first tested in humans from 1995 to 2007 found an average clinical trial duration of 116 months (9.7 years).[29] Because many biologic drugs are intended to treat serious conditions or life–threatening diseases, trials to establish effectiveness of these medicines can take longer than average. Biologic drugs intended for rare diseases face the additional hurdle of recruiting enough patient volunteers, which can lengthen the timeline.[30] Moreover, in some therapeutic

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26. 42 U.S.C. § 262 (a)(2)(C) (2012) (licensure standard for biologics); Investigational New Drug Application, 21 C.F.R. § 312.22 (2016) (showing required to start clinical trials).

27. 21 C.F.R. § 312.21 (2016) (phases of an investigation).

28. Joseph A. DiMasi and Henry G. Grabowski, *The Cost of Biopharmaceutical R&D: Is Biotech Different?*, 28 MANAGERIAL & DECISION ECON. 469, 475 (2007).

29. Joseph A. DiMasi *et al.*, *Innovation in the Pharmaceutical Industry: New Estimates of R&D Costs*, 47 J. HEALTH ECON. 20 (2016).

30. *See, e.g.*, Meng Tan *et al.*, *Using Registries to Recruit Subjects for Clinical Trials*, 41 CONTEMP. CLIN. TRIALS 31, 36 (2015); INSTITUTE OF MEDICINE, TRANSFORMING CLINICAL RESEARCH IN THE UNITED STATES: CHALLENGES AND OPPORTUNITIES 35–36 (National Academies Press 2010) ("When patient recruitment is impeded, the

areas for which biologic drugs offer significant potential, clinical trials are increasing in duration. For instance, one recent study reported that the median oncology clinical trial duration increased on average 16 months from 2002 to 2014, an increase of 69 percent.[31]

The clinical trial process has a high risk of failure. Laboratory and animal data may not accurately predict human response, and a biologic drug may fail when the company starts testing in humans — either because it does not work, or because the overall risk–benefit profile is not favorable in humans.[32] Adjustments to the formulation, dose, and manufacturing process may be necessary to ensure a safe and effective medicine, further protracting the drug development timeline.[33] Ultimately the attrition rate for new medicines is extremely high.[34] The FDA

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trial is delayed, sometimes by years, until the number of patients required by the study protocol can be enrolled.").

31. Moe Alsumidaie & Peter Schiemann, *Why Are Cancer Clinical Trials Increasing in Duration?* Applied Clinical Trials, Aug. 31, 2015, *available at* http://www.appliedclinicaltrialsonline.com/why-are-cancer-clinical-trials-increasing-duration (last accessed March 1, 2017).

32. François Curtin & Pierre Schulz, *Assessing the Benefit: Risk Ratio of a Drug – Randomized and Naturalistic Evidence*, 13 Dialogues in Clinical Neuroscience 183, 184 (2011).

33. Comparability of Human Biological Products, *supra* note 25 (describing testing that must accompany manufacturing changes made prior to approval and recommending consultation with agency to avoid delay).

34. U.S. Gov't Accountability Office, GAO-07-49, New Drug Development: Science, Business, Regulatory, and Intellectual Property Issues Cited as Hampering Drug Development Efforts

approves fewer than ten percent of drugs that enter clinical trials.[35] The risk of failure is even higher in some therapeutic areas commonly treated by biologic drugs. For instance, the probability of a cancer drug development program succeeding even after promising preliminary animal studies is roughly 1 in 20.[36] Drugs directed towards disorders of the central nervous system (CNS) have a success rate lower than all drugs in development – a dismal 6.2 percent of the CNS drugs that entered human trials between 1995 and 2007 were approved.[37] The numbers for Alzheimer's disease are particularly grim. Although 244 drugs directed to Alzheimer's disease (including 76 biologics) were tested from 2002–2012, only one was

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25 (2006) (noting that "clinical trial failure rates [increased] from 82 percent during the period 1996 through 1999, to 91 percent during the period 2000 through 2003"); Ismail Kola & John Landis, *Can The Pharmaceutical Industry Reduce Attrition Rates?*, 3 NATURE REV. DRUG DISCOVERY 711 (2004) (noting that success rate in phase 3 dropped from 80 percent in 1995 to 50 percent in 2005).

35. BIOTECHNOLOGY INNOVATION ORGANIZATION (BIO), CLINICAL DEVELOPMENT SUCCESS RATES 2006–2015 7 (2016) [hereinafter BIO, CLINICAL DEVELOPMENT SUCCESS RATES], *available at* https://www.bio.org/sites/default/files/Clinical%20Development%20Success%20Rates%202006-2015%20-%20BIO,%20Biomedtracker,%20Amplion%202016.pdf (reporting a 63.2 percent chance of progressing to phase 2 and a 30.7 percent chance of progressing to phase 3); *see also* DiMasi, *supra* note 29, at 24 (using a different data set, reporting a 59.5 percent chance of progressing to phase 2 and a 21.1 percent chance of progressing to phase 3).

36. BIO, CLINICAL DEVELOPMENT SUCCESS RATES, *supra* note 35, at 13.

37. TUFTS CENTER FOR THE STUDY OF DRUG DEVELOPMENT, TUFTS UNIVERSITY, IMPACT REPORT, 16/6, 1 (2014).

approved.[38] Several promising biologic drugs to combat Alzheimer's disease failed in the most costly stage of clinical testing, phase 3 trials.[39]

The high attrition rate, which includes not only these phase 3 failures but a high number of phase 2 washouts, force biopharmaceutical firms to recoup their investment in innovative activity from the sales of any successful biologic drugs in their pipeline. Reducing the likelihood of a positive return on this overall investment from the few biologic drugs that succeed, or creating substantial uncertainty about the ability to realize return on investment, will discourage firms from pursuing biopharmaceuticals in the first instance. This could in turn cost the United States its position as the world leader in medical innovation.

C. Biologic drug innovation depends on patent protection

Decades of empirical research confirm that the success of the biopharmaceutical sector depends on the availability of meaningful patent protection.[40] The

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38. Jeffrey L. Cummings *et al.*, *Alzheimer's Disease Drug–Development Pipeline: Few Candidates, Frequent Failures*, 6 ALZHEIMER'S RESEARCH & THERAPY 37, 41 (2014).

39. *See e.g.*, Rik Vandenberghe *et al.*, *Bapineuzumab For Mild to Moderate Alzheimer's Disease in Two Global, Randomized, Phase 3 Trials*, 8 ALZHEIMER'S RESEARCH & THERAPY 18 (2016).

40. *See e.g.*, Edwin Mansfield, *Patents and Innovation: An Empirical Study*, 32 MGMT. SCI. 173, 174–75 (1986) (reporting finding that 65 percent of new pharmaceuticals would not have been introduced absent patent protection); James Bessen & Michael J.

patent system encourages firms to make socially valuable investments in research and development that they would not otherwise make. It promotes investment in innovation, through the protection of property rights in inventions. These property rights, though limited in duration, allow innovators to recoup and profit from their investments in innovative activity.

As explained in Section IB above, biologic drugs require a significant and risky investment in premarket research before commercialization. With the enactment of the BPCIA, Congress has permitted FDA to approve biosimilar drugs twelve years after innovator product approval.[41] At the end of this regulatory exclusivity period, however, the average biologic drug will not have recouped the investment required to bring it to market. Studies indicate that biotechnology companies typically recover their investments between 12.9 and 16.2 years

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Meurer, PATENT FAILURE: HOW JUDGES, BUREAUCRATS, AND LAWYERS PUT INNOVATORS AT RISK (2008) (noting the extreme reliance on patent incentives for pharmaceutical sector compared to other technological sectors); Adam B. Jaffe & Josh Lerner, INNOVATION AND ITS DISCONTENTS: HOW OUR BROKEN PATENT SYSTEM IS ENDANGERING INNOVATION AND PROGRESS, AND WHAT TO DO ABOUT IT (Princeton Univ. Press 2007) (noting that patent provide incentives for costly drug development which otherwise not occur); J. John Wu & Stephen J. Ezell, *How National Policies Impact Global Biopharma Innovation: A Worldwide Ranking*, INFORMATION TECHNOLOGY & INNOVATION FOUNDATION 5 (2016), *available at* https://itif.org/publications/2016/04/07/how-national-policies-impact-global-biopharma-innovation-worldwide-ranking (showing correlation between effective intellectual property protection policies and life science innovation).

41. 42 U.S.C. § 262 (k)(7) (2012).

after approval.[42] Moreover, biosimilar drugs can now reach the market more quickly and on the basis of a smaller investment. This allows biosimilar firms to provide their competing products at lower cost.[43] Further, if FDA deems a biosimilar drug interchangeable with the innovator's product, state laws may shift consumers automatically to the innovator's competition.[44] Without some way to delay the market entry of these competing products, innovator companies will be unable to recoup their investments and will presumably shift their focus from biologic drugs to other opportunities with higher likelihoods of rational returns on investment.

Biologic drugs account for over one–third of the medicines in clinical trials or awaiting FDA approval.[45] Today the industry is tackling a variety of complex diseases and conditions that desperately need improved treatments, including metastatic renal cancer, pancreatic

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42. Henry Grabowski, *Follow–on Biologics: Data Exclusivity and the Balance between Innovation and Competition*, 7 NATURE REV. DRUG DISCOVERY 479 (2008); *see generally* Erika Lietzan, *The Myths of Data Exclusivity*, 20 LEWIS & CLARK L. REV. 91, 156–160 (2016).

43. Lietzan, *supra* note 42, at 108–109.

44. *See* 42 U.S.C. § 262 (k)(4), § 262(i); RICHARD CAUCHI, STATE LAWS AND LEGISLATION RELATED TO BIOLOGICAL MEDICATIONS AND SUBSTITUTION OF BIOSIMILARS, NATIONAL CONFERENCE OF STATE LEGISLATURES (2016), *available at* http://www.ncsl.org/documents/health/Biologics_BiosimilarsNCSLReport2015.pdf.

45. INT'L TRADE ADMIN., U.S. DEPARTMENT OF COMMERCE, 2016 PHARMACEUTICALS TOP MARKETS REPORT 4 (2016), *available at* http://trade.gov/topmarkets/pdf/Pharmaceuticals_Executive_Summary.pdf.

cancer, glioblastoma, *C. difficile* infections, spinal cord injuries, amyotrophic lateral sclerosis (ALS), soft tissue sarcoma, Merkel cell carcinoma, systemic sclerosis, and multiple myeloma.[46] Meaningful patent protection remaining after FDA approval ensures that investors will tackle such complex and risky projects.[47] With several biosimilar drugs approved today, and more than five dozen biosimilars in development,[48] U.S. biopharmaceutical firms need to know that their patent rights will be enforceable and that a meaningful return on investment will be possible.

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46. PhRMA, 2016 MEDICINES IN DEVELOPMENT FOR RARE DISEASES (2016), *available at* http://phrma-docs.phrma.org/sites/default/files/pdf/medicines-in-development-drug-list-rare-diseases.pdf.

47. *See* Lybecker, *supra* note 23, at 1430.

48. Michael Mezher, *FDA Officials Share Best Practices for Biosimilar Development*, REGULATORY AFFAIRS PROFESSIONALS SOCIETY (Oct. 28, 2016) http://www.raps.org/Regulatory-Focus/News/2016/10/28/26093/FDA-Officials-Share-Best-Practices-for-Biosimilar-Development/ (noting that 66 biosimilars were in development at the end of October 2016).

II. THE MANDATORY INFORMATION EXCHANGE PROCESS IN SECTION 351(l) OF THE PUBLIC HEALTH SERVICE ACT (PHSA) ENSURES THAT INNOVATORS HAVE A MEANINGFUL OPPORTUNITY TO ENFORCE THEIR PATENT RIGHTS

A. Like the Hatch–Waxman Act, the BPCIA made changes to the drug approval and patent statutes to ensure that patent owners could enforce their patents without suffering permanent loss due to infringing market launch

Resolving patent infringement issues prior to market entry of generic and biosimilar drugs pursuant to the procedures of the Hatch–Waxman Act and the BPCIA, respectively, ensures that innovators benefit from meaningful enforcement of their patent property rights. Generic and biosimilar applicants enjoy the ability to freeride on an innovator's preclinical and clinical research. Their research and development costs are significantly lower than an innovator's, and they offer aggressive price competition. As a result, generic drugs immediately capture most of the marketplace.[49] Like generic drugs, biosimilar drugs will be able to compete on the basis of price using the economic advantages derived from copying rather than innovating.

A biopharmaceutical innovator never fully recovers its market power after a generic company launches

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49. Henry Grabowski *et al.*, *Recent Trends in Brand–Name and Generic Drug Competition*, 17 J. OF MED. ECON. 1, 6–7 (2013).

its infringing product. even if the infringing product is later removed from the market.[50] Damages for past infringement by a generic drug company do not make the innovator whole. Put another way, when a generic company launches an infringing product, the innovator's ability to recover its high–risk investment in the research and development that led to the new medicine in question is permanently compromised. The Hatch–Waxman Act thus links generic drug approval to the resolution of any patent infringement issues presented by the generic drug.[51] This ensures that an innovator has a meaningful opportunity to enforce its patents against an infringing generic drug *before* that drug enters the marketplace and permanently reduces the innovator's return on investment. Premarket

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50. *See, e.g.* David Manspeizer, *The Law on Damages in Generic Drug Launches Remains Vague*, NEW YORK L. J., Jan. 6, 2014, at 11 (describing the potential losses the patentee may experience even after an infringing generic product is removed from the market place, including the inability to recover prior sales levels, pricing levels, and market share); *see also Sanofi-Synthelabo v. Apotex, Inc.*, 470 F.3d 1368, 1382 (Fed. Cir. 2006) (affirming preliminary injunctive relief that was based in part on finding that innovator "would suffer irreversible price erosion in light of a complex pricing scheme that is directly affected by the presence of the generic drug in the market"); *Purdue Pharma L.P. v. Boehringer Ingelheim GMBH*, 237 F.3d 1359, 1368 (Fed. Cir. 2001) (affirming lower court's finding of irreparable harm on the basis of testimony of economics expert that launch of infringing product would result in price erosion and loss of market position).

51. It accomplishes this linkage by requiring innovators to identify the relevant patents, requiring a generic drug company to determine whether it wishes to contest infringement (or validity) or defer launch until patent expiry, staying approval of the generic drug if the generic drug company chooses to contest a patent and the innovator chooses to enforce the patent, and prohibiting FDA approval of the generic drug until patent expiry if that drug infringes a patent. *See generally* 21 U.S.C. § 355 (j)(5) (2012).

patent litigation for biologic drug innovators — made possible by the BPCIA's amendments to § 351(l) of the PHSA and § 271 of the Patent Act — accomplishes the same objective.

Premarket resolution of patent infringement disputes has long been understood to also benefit generic applicants, by allowing them to enter the marketplace without incurring any risk of patent infringement damages. The Hatch–Waxman Act included a new and "highly artificial" act of infringement in § 271 (e)(2) of the Patent Act for the specific purpose of making it possible for a court to entertain a patent infringement action prior to generic drug market entry.[52] Similarly, the BPCIA amended § 271(e)(2) to add a corresponding artificial act of infringement tied to submission of biosimilar applications.[53] The Patent Act further provides that damages may be awarded against the infringer only in the event of commercial manufacture, use, or sale.[54] The artificial acts of infringement added to the Patent Act ensure that generic and biosimilar applicants can resolve questions of infringement and patent validity before being exposed to infringement liability damages, while at the same time providing the innovator a meaningful opportunity to enforce its patent rights before being exposed to the irreparable harm of an infringing market launch.[55]

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52. *See Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 676–679 (1990); *see also* 35 U.S.C. § 271 (e)(2)(A) (2012).

53. 35 U.S.C. § 271 (e)(2)(C).

54. *Id.* § 271, 496 U.S. at 678.

55. The new *inter partes* review (IPR) procedures permit a premarket administrative challenge to biologics patents at the U.S. Patent and Trademark Office on terms that are considerably more

B. The premarket patent procedures in the PHSA depend on a single act that must be taken by the biosimilar applicant

Premarket patent litigation regarding biosimilar copies of biologic drugs begins with a premarket information exchange process that depends on the biosimilar applicant providing information to the innovator. This process is triggered when FDA notifies the biosimilar applicant that its application has been accepted for review.[56] At this point, the biosimilar applicant "shall" provide a copy of its application to the biologic drug innovator, referred to in the PHSA as the "reference product sponsor," along with information describing its manufacturing process.[57] Every subsequent step in the process that culminates in the innovator bringing its patent infringement case, as laid out in §§ 351(l)(3) through 351(l)(6) of the PHSA, is measured from the moment the biosimilar applicant provides its application to the innovator.[58]

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favorable for generic and biosimilar companies than conventional federal court litigation. The availability of IPR may have made the premarket litigation schemes written into the drug approval statutes less appealing to these firms. *See* Joanna Shepherd, *Disrupting The Balance: The Conflict Between Hatch–Waxman and Inter Partes Review*, 6 NYU J. INTELL. PROP. & ENT. L. 14, 41 (2016) ("Although IPR challenges to pharmaceutical patents do not yet occur in large numbers, their popularity is increasing swiftly.").

56. PHSA § 351(l)(2), codified at 42 U.S.C. § 262 (l)(2) (2012).

57. 42 U.S.C. § 262 (l)(2)(A).

58. *Id.* §§ 262 (l)(3)–(6).

- The biologic drug innovator must comply with paragraph (3)(A) within 60 days of that point;

- The biosimilar applicant must comply with paragraph (3)(B) within another 60 days of that point;

- The biologic drug innovator must comply with paragraph (3)(C) within another 60 days of that point;

- The parties must negotiate a narrow list of patents for immediate patent litigation, in accordance with paragraph (4), for another 15 days from that point;

- If the parties fail to reach an agreement within 15 days, the biosimilar applicant must comply with paragraph (5)(A), and the parties must comply with paragraph (5)(B) within another 5 days;

- And then, within another 30 days, the biologic drug innovator must bring patent infringement litigation under paragraph (6).[59]

Consequently if the biosimilar applicant does not perform the initial, pivotal step in paragraph (2)(A) — providing a copy of its application and manufacturing information to the biologic drug innovator — the deadlines in these provisions are meaningless and the entire process fails *ab initio.*

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59. *Id.* §§ 262 (l)(3)–(6).

Moreover, every substantive obligation in the process set forth in § 351(l) is made possible only because the biosimilar applicant has performed this initial step.

- The application and manufacturing information form the basis of the biologic drug innovator's list of patents — provided under paragraph (3)(A) — that could reasonably be asserted in litigation or potentially licensed.

- The application and manufacturing information form the basis of the biologic drug innovator's claim-by-claim statement — provided under paragraph (3)(C) — of the factual and legal basis for its opinion that each patent will be infringed by the commercial marketing of the biosimilar.

- The application and manufacturing information, and resulting patent list and infringement opinions, necessarily inform the biologic drug innovator's position in the negotiations under paragraph (4) regarding which patents it wishes to litigate immediately.

- The application and manufacturing information form the basis for the complaint in the patent infringement litigation brought under paragraph (6).[60]

If the biosimilar applicant does not perform the initial, pivotal step in paragraph (2)(A), none of these subsequent obligations can be met and the benefits to both parties of the premarket patent procedures laid out in the BPCIA are lost.

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60. *Id.* §§ 262 (l)(3)–(4), (6).

C. Rejecting the systematic process created by Congress in favor of *ad hoc* and poorly informed declaratory judgment actions would be contrary to the public interest

In addition to ensuring meaningful protection of the biologic drug innovator's patents and providing pre–liability resolution of patent infringement questions for biosimilar applicants, the pre–litigation information exchange process in § 351(l) furthers the goals of litigation efficiency and conservation of judicial resources. The joint construction of a master list of potentially implicated patents and the winnowing of patents for litigation under paragraphs (3)–(5) of § 351(l) permit immediate and more accurate identification of patents to be enforced. This process can eliminate time–consuming discovery procedures and at least some discovery disputes, making the actual patent litigation under the Patent Act more efficient. It also narrows the scope of the litigation, which conserves both private and judicial resources.

The BPCIA scheme would be thwarted if the information exchange step in paragraph (2)(A) were optional. If a biosimilar applicant elected to ignore paragraph (2)(A), the biologic drug innovator might not learn of the pending biosimilar application.[61] Even if, as here, the innovator knew of the application, it might know nothing more than the fact that FDA had accepted the application for review. The biologic drug innovator's

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61. FDA regulations have long precluded the agency from disclosing the fact of one pending application unless it has previously been publicly disclosed or acknowledged. 21 C.F.R. §§ 601.51 (b), 314.430 (b).

only option — prior to launch of the potentially infringing product, which would create a federal cause of action under 35 U.S.C. § 271 (a) — would be to seek a declaratory judgment of infringement invoking § 271(e)(2)(C)(ii). Under these circumstances the biologic drug innovator would frequently have little or no information on which to base its identification of the patents that the biosimilar applicant might be infringing. This would result in a system of *ad hoc* and poorly informed (or even totally uninformed) declaratory judgment actions, supplemented by equally uninformed attempts to obtain preliminary injunctions in the final months before potential biosimilar launches.

D. Section 271(e)(2)(C)(ii) of the Patent Act protects biologic drug innovators in the event biosimilar applicants fail to comply with the statute, but it does not excuse compliance with § 351(l) of the PHSA

The Federal Circuit fundamentally misunderstood the role of § 271 (e)(2)(C)(ii) when it reasoned that biosimilar applicants need not comply with the initial step of the premarket information exchange.[62] The special act of infringement in clause (ii) reflects a fundamental difference between the Hatch–Waxman Act and the BPCIA.

As this Court explained nearly thirty years ago, the artificial act of infringement in § 271(e)(2)(C) was made necessary because Congress had also in the same legislation enacted a provision, § 271(e)(1), exempting the

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62. *Amgen Inc. v. Sandoz Inc.*, 794 F.3d 1347, 1355–57 (Fed. Cir. 2015).

manufacture or use of a patented invention from patent infringement if these acts were done for the purpose of obtaining FDA approval.[63] This provision overruled in part a ruling of the Federal Circuit and affirmatively "disabled" patent owners from establishing acts of infringement against competitors prior to market entry.[64] As a result of the *Bolar* provision, "an act of infringement had to be created," or the premarket patent litigation provisions of the Act would not function.[65]

At the same time, the Hatch–Waxman Act gave FDA a role in ensuring that generic applicants complied with the statutory requirement to address the patents claiming the reference drug. Compliance is achieved by requiring the innovator to provide a list of the relevant patents to the agency, which the agency then publishes in the "Orange Book," and by requiring the generic applicant to provide its views on those patents *to the agency*.[66] Further, if the

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63. *Eli Lilly*, 496 U.S. at 678 (citing 35 U.S.C. § 271(e)(1), which provides that it is not an act of infringement to make or use a patented invention solely for reasons reasonably related to the development and submission of a marketing application).

64. *Eli Lilly*, 496 U.S. at 678; 35 U.S.C. § 271(e)(1) is referred to as the "Bolar" provision after the Federal Circuit decision in question. *Roche Products, Inc. v. Bolar Pharm. Co.*, 733 F.2d 858 (Fed. Cir. 1984).

65. *Eli Lilly*, 496 U.S. at 678.

66. 21 U.S.C. § 355 (b)(1) (2012) (requiring the innovator to provide patent information as part of its new drug application); § 355 (j)(2)(A)(vii) (requiring generic applicants to address patents claiming the reference drug or a method of using the reference drug). FDA, APPROVED DRUG PRODUCTS WITH THERAPEUTIC EQUIVALENCE EVALUATIONS (37th ed. 2017) ("Orange Book"), *available at* https://

generic applicant intends to launch prior to expiration of the innovator's patents, it must affirmatively state to FDA that it will notify the patent owner of its intention.[67] The agency polices compliance and will not accept generic applications that fail to address patents listed by the innovator in the Orange Book.[68]

FDA does not play this role under the BPCIA. The agency does not have a list of relevant biologic drug patents. The biosimilar applicant does not include patent information in its application. Nor does the biosimilar applicant indicate to FDA whether it intends to launch prior to expiry of any patents. The agency does not police compliance. FDA has no way of knowing whether the biosimilar applicant provided its application and manufacturing information to the biologic drug innovator or complied with any other requirement of § 351(l).

If a biosimilar applicant complies with the information exchange process mandated by the BPCIA, it too must take a position with respect to each relevant patent.[69] Just as under the Hatch–Waxman Act, if the biosimilar applicant challenges a patent by seeking to launch prior to patent expiry, submitting its application constitutes an

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www.fda.gov/downloads/Drugs/DevelopmentApprovalProcess/UCM071436.pdf (listing patents identified by innovators in their applications).

67. 21 U.S.C. § 355 (j)(2)(B)(i).

68. *See* FDA, GUIDANCE FOR INDUSTRY, ANDA SUBMISSIONS — REFUSE-TO-RECEIVE STANDARDS 2 (2016), *available at* https://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm370352.pdf.

69. 42 U.S.C. § 262 (l)(3)(B) (2012).

act of infringement.[70] But the artificial act of infringement is tied to the patents identified through that information exchange process.[71] As a result, if the biosimilar applicant *fails* to comply with the information exchange process — which FDA does not enforce — the disability enacted by the Hatch–Waxman Act remains in place. Section 271(e)(2)(C)(ii) simply removes the disability, allowing a biologic drug innovator to establish an artificial act of infringement in the event that it learns that an infringing application has been filed. Failure to remove the disability with an artificial act of infringement would effectively penalize the biologic drug innovator for the biosimilar applicant's failure to comply with the process laid out in § 351(l). The Federal Circuit misunderstood the fundamental purpose of § 271(e)(2)(C)(ii) when it concluded that Congress intended to excuse biosimilar applicants from compliance with those provisions.[72]

III. CROSS-RESPONDENT IS ATTEMPTING TO SECURE FROM THE COURTS AN OUTCOME THAT IT WAS UNABLE TO OBTAIN FROM CONGRESS

A. The development of the BPCIA provided stakeholders with ample opportunity to shape the patent provisions of the legislation

By any reasonable measure, the process culminating in enactment of the BPCIA in 2010 provided a robust

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70. 35 U.S.C. § 271 (e)(2)(C)(i) (2012).

71. *Id.*

72. *See Amgen Inc. v. Sandoz Inc.*, 794 F.3d 1347, 1355 (Fed. Cir. 2015).

and participatory framework for stakeholders to provide input. The statute was enacted after nearly a decade of stakeholder discussions — within the industries, before FDA, in dockets at the agency, in scientific and legal journals, in legislative hearings, and on Capitol Hill more generally — about every key scientific, legal, and policy issue that needed to be addressed, as researched and published by an author of this *amici* brief.[73] Every provision of the final legislation was publicly vetted for several years.[74] The process afforded biosimilar manufacturers, including Cross–Respondent Sandoz and its parent company Novartis,[75] many opportunities over many years to address the scope, contours, and design of the patent information exchange and litigation provisions.[76]

Stakeholders repeatedly addressed whether and how patent disputes should be resolved prior to biosimilar market entry. For example, witnesses at Congressional hearings in 2007 discussed three different approaches: one witness supported voluntary premarket patent litigation, another recommended that biosimilars not be approved until all patent issues were resolved, and another recommended that patent issues be removed

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73. *See generally* Krista Hessler Carver, Jeffrey Elikan & Erika Lietzan, *An Unofficial Legislative History of the Biologics Price Competition and Innovation Act of 2009*, 65 FOOD & DRUG L.J. 671–818 (2010).

74. *Id.*

75. *See, e.g., The Sandoz Brand*, SANDOZ.COM https://www.sandoz.com/about-us/who-we-are/sandoz-brand (last visited March 14, 2017) ("Sandoz is a division of the Novartis Group and a global leader in generic pharmaceuticals and biosimilars.").

76. *See, e.g.*, Carver, *supra* note 73, at 671–818.

from the legislation altogether.[77] In early 2008, the House Subcommittee on Health solicited the written views of 35 organizations on a variety of questions relating to possible biosimilar legislation specifically in order to "understand more fully the range of perspectives, concerns, and objectives that might be addressed" in a legislative proposal.[78] The solicitation included a series of questions relating to patent protection, patent infringement, and the procedures that should be included to allow patent owners to identify potential patent infringement claims and ensure timely resolution of those disputes.[79] The advisability and design of patent dispute resolution provisions were addressed again in hearings in 2008 and 2009.[80] The final language of the patent provisions reflected years of such discussions.

B. Novartis, the parent company of Cross-Respondent Sandoz, provided input during these years and consistently took the position that patent litigation should be decoupled from the biosimilar regulatory pathway

Throughout the lengthy legislative information-gathering process, Novartis/Sandoz consistently opposed any legislation that combined the biosimilar regulatory pathway with patent resolution processes. For example, in a 2007 Senate hearing on biosimilars, Ajaz

77. *Id.* at 736–737.

78. Letter from Frank Pallone, Jr., Chairman, & Nathan Deal, Ranking Member, Subcomm. on Health, Comm. on Energy & Commerce, U.S. House of Reps., to 35 groups (Apr. 3, 2008).

79. *Id.* at 6.

80. Carver, *supra* note 73, at 789, 798–802.

S. Hussain, Ph.D., Vice President and Global Head of Biopharmaceutical Development at Novartis, testified that patent litigation should be kept completely separate from the biosimilar regulatory process.[81] In fact, Dr. Hussain opined that such "decoupling" was "essential" to provide biosimilar drugs to patients in a timely manner. Instead of the mutual information exchange now present in the language of the BPCIA, Dr. Hussain called for a "non–patent research incentive" or other types of proceedings to help resolve biologic drug patent rights.[82]

The following year, in response to the House Subcommittee on Health leadership's letter requesting input from stakeholders, then–President and Chief Executive Officer, Paulo Costa made clear Novartis opposed provisions regarding premarket information disclosure and patent resolution processes.[83] Mr. Costa argued that, instead of a mutual disclosure of information, patent owners should be able to enforce their patents only after launch of the biosimilar drug.[84]

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81. *See Follow-On Biologics: Hearing on Examining Food and Drug Administration Follow-On Biologics, Generally Referred to As a Biotechnology Derived Protein Drug (Or Biologic) That is Comparable to a Novel, Previously Approved Biologic and That is Approved With less Supporting Data Than the Innovator Biologic Before the Comm. On Health, Ed., Labor, and Pensions*, 110 Cong. 36 (2007).

82. *Id.*

83. Letter from Paulo Costa, CEO, Novartis Corp., to Frank Pallone, Jr. and Nathan Deal, H. Subcomm. On Health, 29 (May 1, 2008).

84. *Id.*

Later in 2008, responding to a request for comment from the Federal Trade Commission (FTC), incoming President and Chief Executive Officer Robert Pelzer[85] echoed Novartis' corporate refrain, stating "[T]here is absolutely no need, and indeed there would be serious downsides, to coupling FDA's regulatory review of FOBs ["Follow-On Biologics"] to the exercise of patent rights."[86] Mr. Pelzer recommended a statutory notification process between the biosimilar applicant and the biologic drug innovator, but only to the extent it might provide an "orderly" entry into "traditional patent remedies in court."[87]

Amici submit that Novartis' position was a contrarian one, even for a generics company. For example, during a workshop organized by the FTC, William Schultz, who represented the generic industry throughout the legislative process, stated that the goal should be to develop a system so that "the first day that the biosimilar, the biogeneric, is ready to be approved, all issues regarding patents that have been identified that would preclude it

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85. Mr. Pelzer assumed the role of President and CEO of Novartis in September 2008. *See* Robert E. Pelzer, Executive Profile, BLOOMBERG, http://www.bloomberg.com/research/stocks/private/person.asp?personId=8320773&privcapId=34924763 (last visited March 14, 2017).

86. Letter from Robert Pelzer, CEO Novartis, to the Federal Trade Commission, at 19 (Sept. 29, 2008), *available at* https://www.ftc.gov/sites/default/files/documents/public_comments/emerging-health-care-competition-and-consumer-issues-537778-00009/537778-00009.pdf.

87. *Id.*

from marketing, have been resolved."[88] Meanwhile, at that same meeting, Novartis' Vice–President of IP Strategy Ken Goldman was the "lone dissenter," reiterating his company's view that "pre–approval patent resolution is contrary to the principles of competition."[89]

Based on the public engagement noted above, it is clear that Novartis/Sandoz was afforded (and seized upon) ample opportunities to convey its preferred approach to a regulatory pathway for biosimilar drugs. Nevertheless, as described below, after fairly considering the Novartis/Sandoz approach of decoupling biosimilar approval from the resolution of patent infringement issues, Congress rejected this approach when enacting the BPCIA.

C. Congress knowingly rejected the approach preferred by Novartis/Sandoz

Between the fall of 2006, when Representative Waxman introduced the first biosimilar bill, and March of 2010, when President Obama signed the BPCIA into law, Congress considered at least eight distinct bills and several further amendments directed to biosimilar drugs.[90] These proposals took varying approaches to the

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88. Cathy Dombrowski, *Follow–On Biologic Stakeholders Agree On Patent Resolution, Differ On Details*, THE PINK SHEET (Dec. 8, 2008), https://pink.pharmamedtechbi.com/PS050412/FollowOn-Biologic-Stakeholders-Agree-On-Patent-Resolution-Differ-On-Details.

89. *Id.*

90. *See generally* Carver, *supra* note 73, at 716–806; *see, e.g.*, Access to Life-Saving Medicine Act H.R. 1038, 110th Cong. (2007); Patient Protection and Innovative Biologic Medicines Act of 2007, H.R. 1956, 110th Cong. (2007); Affordable Biologics for Consumers

questions of whether and how patent infringement issues might be handled prior to biosimilar market entry. For example, the earliest bill in August 2006 — introduced by Representative Waxman — left it to the discretion of the biosimilar applicant whether to pursue resolution of patent issues prior to market launch.[91] A biosimilar applicant could not have been compelled, "by court order or otherwise," to begin the patent resolution process described in the bill.[92]

Later, new approaches were offered. One such approach, a bill introduced by Rep. Inslee, omitted patent litigation provisions altogether.[93] Another bill, introduced by Senator Gregg, set out a mandatory premarket litigation clearance process that involved FDA directly.[94] The agency would have published a Notice in the Federal Register that a biosimilar application had been filed. The biologic drug innovator would have been entitled to request information directly from the biosimilar applicant in order to determine whether its patents had been infringed. If the biologic drug innovator concluded that any of its patents would be infringed, the biosimilar applicant would be required to decide whether to challenge this conclusion (which would constitute an artificial act of infringement) or wait for patent expiry before launching its biosimilar copy of the patented biologic drug.

Act, S. 1505, 110th Cong. (2007); Biologics Price Competition and Innovation Act of 2007, S. 1695, 110th Cong. (2007); Access to Life-Saving Medicine Act, H.R. 6257, 109th Cong. (2006).

91. H.R. 6257, § 3(a)(2) (proposed PHSA § 351(k)(16)(E)).

92. Carver, *supra* note 73, at 721.

93. H.R. 1956, 110th Cong. (2007).

94. S. 1505, § 2(a)(2) (proposed PHSA § 351(k)(8)).

Ultimately, Congress did not enact either of these approaches. Instead, the legislature adopted the approach developed by a bipartisan group of Senators that utilized substantial stakeholder input and which was introduced in 2007 as Senate Bill 1695.[95] The patent litigation regime in this bill, as described hereinabove in Section II, creates a premarket patent litigation procedure that starts with, and depends upon, mandatory disclosure by the biosimilar applicant within 20 days of FDA's acceptance of its biosimilar application. Novartis/Sandoz had ample opportunity to state its case before Congress and, indeed, forcefully urged a different approach. Novartis/Sandoz failed to convince Congress; *for example*, Representative Inslee's bill — which lacked patent provisions — never found any legislative traction. Representative Waxman's bill, introduced in two successive years, expressly stated that participation in the scheme would be "left entirely to the discretion of the applicant," and this proposal never garnered enough votes for passage.[96]

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95. "[A] variety of approaches to key issues were drafted, considered repeatedly, and in the end not adopted. This fact must influence interpretation of the final enacted provisions." Carver, *supra* note 73, at 816.

96. H.R. 6257 § 3(a)(2) (proposed PHSA § 351(k)(16)(E)); H.R. 1038 § 3(a)(2) (proposed PHSA § 351(k)(16)(E)).

D. Novartis/Sandoz is attempting to achieve before the courts what it could not achieve before Congress

When the BPCIA was enacted as part of the Affordable Care Act in 2010, many generic companies applauded; Sandoz did not.[97] Instead, its CEO Jeffrey George complained that the BPCIA was "unfair to generic companies [who] would be required to hand over our dossiers to our competitors years before the product comes to market" and questioned whether Sandoz would even consider using the newly created pathway to bring their follow–on biologic drugs to market.[98]

Comments like those made by its executives, demonstrate that Novartis/Sandoz fully understands that the BPCIA requires mutual information disclosure, and that the company is taking advantage of the abbreviated biosimilar pathway while ignoring the disclosure provisions that it well understands are mandatory — in short, acting as if Congress had in fact adopted the company's long–advocated position. *Amici* submit that Cross–Respondent is engaging this Court in an attempt to undermine the legislative process.

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97. *Sandoz Will Steer Clear Of U.S. Biosimilars Pathway, Use Other Applications* 2/6 THE PINK SHEET (May 3, 2010), https://pink.pharmamedtechbi.com/PS052193/Sandoz-Will-Steer-Clear-Of-US-Biosimilars-Pathway-Use-Other-Applications.

98. *Id.* at 3/6 (emphasis added) ("It's not clear that companies like Sandoz and the leading generic companies in the world would use this pathway to go to market.")

Congress heard from Sandoz/Novartis and others who preferred to separate biosimilar approval from biologic drug patent litigation or give biosimilar companies the option whether to participate. Instead, as Novartis/Sandoz is well aware, Congress enacted a mandatory information exchange process and created an artificial act of infringement, allowing biologic drug innovators a meaningful opportunity to enforce their patents prior to market entry of infringing biosimilar drugs. Ultimately, the biosimilars pathway policy was entrusted to, and decided by, the legislature; the courts must take the resulting statute as enacted.[99] Novartis/Sandoz should take its case back to Congress rather than asking this Court for relief that the company failed to secure from the legislature.[100]

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99. *Marbury v. Madison*, 5 U.S. 137, 177 (1803) ("province and duty ... to say what the law is").

100. *Cf. Chevron, U.S.A., Inc. v. Nat. Res. Def. Council, Inc.*, 467 U.S. 837, 864 (1984) (noting that respondents were improperly "waging in a judicial forum a specific policy battle which they ultimately lost in the agency" and that such policy arguments are more properly addressed to legislators).

CONCLUSION

Amici respectfully request that this Court reverse and remand this matter to the Federal Circuit.

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